



**Add value.  
Inspire trust.**

TÜV SÜD Product Service GmbH · Ridlerstr. 65 · 80339 Munich · Germany

Haemonetics Corporation  
125 Summer Street  
02110 BOSTON  
USA

Your reference/letter of	Our reference/name	E-mail	Tel. extension	Date	Page
105829	713278415 PSE200210004483_CL	medical_devices@tuvsud.com	---	2024-04-30	1 of 47

## TÜV SÜD Product Service GmbH Confirmation Letter

**CL 105829 0012 Rev. 00**

**Reference: 713278415 | PSE200210004483\_CL**

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.**

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

**SRN Number: US-MF-000034539**

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below:

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

**Registered Office: Munich**  
Trade Register Munich HRB 85 742  
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Information pursuant to § 2 [1] DL-InfoV  
(Germany) at [tuvsud.com/imprint](http://tuvsud.com/imprint)

**Supervisory Board:**  
Holger Lindner (Chairman)  
**Board of Management:**  
Dr. Walter Reithmaier (CEO)  
Patrick van Welij

**TÜV SÜD Product Service GmbH**  
Application Review  
Ridlerstr. 65  
80339 Munich  
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**TÜV®**



If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see: [www.tuvsud.com/ps-cert?q=cert:CL\\_105829\\_0012\\_Rev.00](http://www.tuvsud.com/ps-cert?q=cert:CL_105829_0012_Rev.00)

In case of inquiries please contact: [medical\\_devices@tuvsud.com](mailto:medical_devices@tuvsud.com)

On behalf of the Notified Body TÜV SÜD Product Service GmbH,  
2024-04-30

TÜV SÜD Product Service GmbH  
Medical and Health Services

  
Monica Zhu (30. April 2024 10:57 EDT)

Monica Zhu  
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH  
Medical and Health Services

  
Konrad Fackler (30. April 2024 16:56 GMT+2)

Konrad Fackler  
Application Reviewer



**Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>Blood Transfusion Filter without transfusion set</b></p> <p><b>Article number:</b> SQ40S</p> <p><b>Basic UDI-DI:</b> 0887691WB0001RY</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Blood Transfusion Filter without transfusion set</b></p> <p><b>Article number:</b> SQ40SE</p> <p><b>Basic UDI-DI:</b> 0887691WB0001RY</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Blood Transfusion Filter Set</b></p> <p><b>Article number:</b> SQ40SK</p> <p><b>Basic UDI-DI:</b> 0887691WB0001RY</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



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<b>Blood Transfusion Filter Set</b>  <b>Article number:</b> SQ40SKLE  <b>Basic UDI-DI:</b> 0887691WB0001RY	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123
<b>Blood Transfusion Filter Set</b>  <b>Article number:</b> SQ40SKTE  <b>Basic UDI-DI:</b> 0887691WB0001RY	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123
<b>Blood Transfusion Filter Set</b>  <b>Article number:</b> SQ40SY  <b>Basic UDI-DI:</b> 0887691WB0001RY	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>NexSys PCS® Plasma Collection System</b></p> <p><b>Article number:</b> PCS-300-INT</p> <p><b>Basic UDI-DI:</b> 081274701PLS0013J</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>BMB PLS Bowls</b></p> <p><b>Article number:</b> 0625B-00</p> <p><b>Basic UDI-DI:</b> 081274701PLS0023L</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>PLS Harness Sets</b></p> <p><b>Article number:</b> 00620-CP</p> <p><b>Basic UDI-DI:</b> 081274701PLS0053S</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>Plasma Bottle w/Saline Adaptor</b></p> <p><b>Article number:</b> 0694S-00</p> <p><b>Basic UDI-DI:</b> 081274701PLS0063U</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>BMB PLS Bowl</b></p> <p><b>Article number:</b> 0625B-JE</p> <p><b>Basic UDI-DI:</b> 081274701PLS0023L</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>HS PLS Bowl</b></p> <p><b>Article number:</b> 625HS-00</p> <p><b>Basic UDI-DI:</b> 081274701PLS0113M</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



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<p><b>PLS Bundled Set w/NaCL w/Vac</b></p> <p><b>Article number:</b> 00627-00</p> <p><b>Basic UDI-DI:</b> 081274701PLS0033N</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>PLS Bundled Set W/ Filter, BMB</b></p> <p><b>Article number:</b> 0792P-00</p> <p><b>Basic UDI-DI:</b> 081274701PLS0033N</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>PLS Bag</b></p> <p><b>Article number:</b> 00690-00</p> <p><b>Basic UDI-DI:</b> 081274701PLS0043Q</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>PLS Bag w/NaCl Spike</b></p> <p><b>Article number:</b> 00692-00</p> <p><b>Basic UDI-DI:</b> 081274701PLS0043Q</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>PLS Bag w/Vac Samp &amp; NaCl Spike</b></p> <p><b>Article number:</b> SA692-00</p> <p><b>Basic UDI-DI:</b> 081274701PLS0043Q</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>PLS Bag w/Vac Sampling</b></p> <p><b>Article number:</b> SC690-00</p> <p><b>Basic UDI-DI:</b> 081274701PLS0043Q</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



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<b>BloodTrack®</b>  <b>Article number:</b> BloodTrack  <b>Basic UDI-DI:</b> 081274701HSS0022R	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123
<b>MCS®+</b>  <b>Article number:</b> 09000-220-E  <b>Basic UDI-DI:</b> 081274701MCS001X5	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123
<b>MCS®+</b>  <b>Article number:</b> 09000-220-ED  <b>Basic UDI-DI:</b> 081274701MCS001X5	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123



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<p><b>MCS®+</b></p> <p><b>Article number:</b> 09000-220-EW</p> <p><b>Basic UDI-DI:</b> 081274701MCS001X5</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>MCS®+</b></p> <p><b>Article number:</b> 09000-220-EW-RU</p> <p><b>Basic UDI-DI:</b> 081274701MCS001X5</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>UPP® Universal Platelet Protocol</b></p> <p><b>Article number:</b> 112320-CS</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



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<p><b>UPP® Universal Platelet Protocol</b></p> <p><b>Article number:</b> 112320-DE</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>UPP® Universal Platelet Protocol</b></p> <p><b>Article number:</b> 112320-EL</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>UPP® Universal Platelet Protocol</b></p> <p><b>Article number:</b> 112320-ES</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>UPP® Universal Platelet Protocol</b></p> <p><b>Article number:</b> 112320-FR</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>UPP® Universal Platelet Protocol</b></p> <p><b>Article number:</b> 112320-IE</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>UPP® Universal Platelet Protocol</b></p> <p><b>Article number:</b> 112320-IT</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>UPP® Universal Platelet Protocol</b></p> <p><b>Article number:</b> 112320-NL</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>UPP® Universal Platelet Protocol</b></p> <p><b>Article number:</b> 112320-NO</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>UPP® Universal Platelet Protocol</b></p> <p><b>Article number:</b> 112320-PL</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



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<p><b>UPP® Universal Platelet Protocol</b></p> <p><b>Article number:</b> 112320-RU</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>UPP® Universal Platelet Protocol</b></p> <p><b>Article number:</b> 112320-SV</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>UPP® Universal Platelet Protocol (UPP A2)</b></p> <p><b>Article number:</b> 118998-CM</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>UPP® Universal Platelet Protocol (UPP A2)</b></p> <p><b>Article number:</b> 118998-CT</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>UPP® Universal Platelet Protocol (UPP A2)</b></p> <p><b>Article number:</b> 118998-DE</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>UPP® Universal Platelet Protocol (UPP A2)</b></p> <p><b>Article number:</b> 118998-ES</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>UPP® Universal Platelet Protocol (UPP A2)</b></p> <p><b>Article number:</b> 118998-FR</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>UPP® Universal Platelet Protocol (UPP A2)</b></p> <p><b>Article number:</b> 118998-FRFR</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>UPP® Universal Platelet Protocol (UPP A2)</b></p> <p><b>Article number:</b> 118998-IE</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>UPP® Universal Platelet Protocol (UPP A2)</b></p> <p><b>Article number:</b> 118998-IT</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>UPP® Universal Platelet Protocol (UPP A2)</b></p> <p><b>Article number:</b> 118998-PT</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>UPP® Universal Platelet Protocol (UPP A2)</b></p> <p><b>Article number:</b> 118998-RO</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



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<p><b>UPP® Universal Platelet Protocol (UPP A2)</b></p> <p><b>Article number:</b> 118998-RU</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>UPP® Universal Platelet Protocol (UPP A2)</b></p> <p><b>Article number:</b> 118998-RUBY</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>UPP® Universal Platelet Protocol (UPP A2)</b></p> <p><b>Article number:</b> 118998-RURU</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>UPP® Universal Platelet Protocol (UPP A2)</b></p> <p><b>Article number:</b> 118998-TR</p> <p><b>Basic UDI-DI:</b> 081274701MCS007XH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Platelet Poor Plasma &amp; Fresh Frozen Plasma Protocol (PPP&amp;FFP)</b></p> <p><b>Article number:</b> 89960-01</p> <p><b>Basic UDI-DI:</b> 081274701MCS011X8</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Platelet Poor Plasma &amp; Fresh Frozen Plasma Protocol (PPP&amp;FFP)</b></p> <p><b>Article number:</b> 89960-02</p> <p><b>Basic UDI-DI:</b> 081274701MCS011X8</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



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<p><b>Platelet Poor Plasma &amp; Fresh Frozen Plasma Protocol (PPP&amp;FFP)</b></p> <p><b>Article number:</b> 89960-03</p> <p><b>Basic UDI-DI:</b> 081274701MCS011X8</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Platelet Poor Plasma &amp; Fresh Frozen Plasma Protocol (PPP&amp;FFP)</b></p> <p><b>Article number:</b> 89960-06</p> <p><b>Basic UDI-DI:</b> 081274701MCS011X8</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Platelet Poor Plasma &amp; Fresh Frozen Plasma Protocol (PPP&amp;FFP)</b></p> <p><b>Article number:</b> 89960-08</p> <p><b>Basic UDI-DI:</b> 081274701MCS011X8</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>Platelet Poor Plasma &amp; Fresh Frozen Plasma Protocol (PPP&amp;FFP)</b></p> <p><b>Article number:</b> 89960-09</p> <p><b>Basic UDI-DI:</b> 081274701MCS011X8</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Platelet Poor Plasma &amp; Fresh Frozen Plasma Protocol (PPP&amp;FFP)</b></p> <p><b>Article number:</b> 89960-12</p> <p><b>Basic UDI-DI:</b> 081274701MCS011X8</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Platelet Poor Plasma &amp; Fresh Frozen Plasma Protocol (PPP&amp;FFP)</b></p> <p><b>Article number:</b> 89960-30</p> <p><b>Basic UDI-DI:</b> 081274701MCS011X8</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>Platelet Poor Plasma &amp; Fresh Frozen Plasma Protocol (PPP&amp;FFP)</b></p> <p><b>Article number:</b> 89960-IEBY</p> <p><b>Basic UDI-DI:</b> 081274701MCS011X8</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Therapeutic Plasma Exchange Protocol (TPE)</b></p> <p><b>Article number:</b> 89967-00</p> <p><b>Basic UDI-DI:</b> 081274701MCS010X6</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Therapeutic Plasma Exchange Protocol (TPE)</b></p> <p><b>Article number:</b> 89967-02</p> <p><b>Basic UDI-DI:</b> 081274701MCS010X6</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>Therapeutic Plasma Exchange Protocol (TPE)</b></p> <p><b>Article number:</b> 89967-03</p> <p><b>Basic UDI-DI:</b> 081274701MCS010X6</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Therapeutic Plasma Exchange Protocol (TPE)</b></p> <p><b>Article number:</b> 89967-06</p> <p><b>Basic UDI-DI:</b> 081274701MCS010X6</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Therapeutic Plasma Exchange Protocol (TPE)</b></p> <p><b>Article number:</b> 89967-12</p> <p><b>Basic UDI-DI:</b> 081274701MCS010X6</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>ACP®215</b></p> <p><b>Article number:</b> 02215-220-E</p> <p><b>Basic UDI-DI:</b> 081274701ACP001RL</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>RBC Glycerolization Set</b></p> <p><b>Article number:</b> 00225-00</p> <p><b>Basic UDI-DI:</b> 081274701ACP002RN</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>RBC De-Glycerol./Cell Wash Set</b></p> <p><b>Article number:</b> 00235-00</p> <p><b>Basic UDI-DI:</b> 081274701ACP004RS</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>RBC De-Glycerol. Set 325mL BMB</b></p> <p><b>Article number:</b> 00236-00</p> <p><b>Basic UDI-DI:</b> 081274701ACP003RQ</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>RBC De-Glycerol./ Cell Wash Set</b></p> <p><b>Article number:</b> 0235P-00</p> <p><b>Basic UDI-DI:</b> 081274701ACP005RU</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>TPE Set (225 mL Latham)</b></p> <p><b>Article number:</b> 0980E-00</p> <p><b>Basic UDI-DI:</b> 081274701MCS009XM</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>TPE Set (225 mL Latham)</b></p> <p><b>Article number:</b> 0981E-00</p> <p><b>Basic UDI-DI:</b> 081274701MCS009XM</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Reservoir, Hard-Shell, 150µ</b></p> <p><b>Article number:</b> 00205-00</p> <p><b>Basic UDI-DI:</b> 081274701CSE002VK</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Reservoir, Hard-Shell, 20µ</b></p> <p><b>Article number:</b> 00220-00</p> <p><b>Basic UDI-DI:</b> 081274701CSE002VK</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<b>Reservoir, Soft Shell, 40µ Filter</b>  <b>Article number:</b> 00240-MTSA  <b>Basic UDI-DI:</b> 081274701CSE0013WG	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123
<b>Reservoir, Soft Shell, 170µ Filter</b>  <b>Article number:</b> 00300-MTSA  <b>Basic UDI-DI:</b> 081274701CSE0013WG	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123
<b>Aspiration / Anticoagulation Set</b>  <b>Article number:</b> 00208-00  <b>Basic UDI-DI:</b> 081274701CSE005VR	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>Aspiration &amp; Anticoagulation Line</b></p> <p><b>Article number:</b> 00208-MT</p> <p><b>Basic UDI-DI:</b> 081274701CSE008VX</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Cell Saver Step Down Adapter</b></p> <p><b>Article number:</b> ATA-A-1000</p> <p><b>Basic UDI-DI:</b> 081274701CSE009VZ</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Waste Bag, 10L</b></p> <p><b>Article number:</b> CSE-B-1000</p> <p><b>Basic UDI-DI:</b> 081274701CSE006VT</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>Vacuum Line, Filtered</b></p> <p><b>Article number:</b> HAR-A-1000</p> <p><b>Basic UDI-DI:</b> 081274701CSE004VP</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Y Set With Extension Line</b></p> <p><b>Article number:</b> 00240-00</p> <p><b>Basic UDI-DI:</b> 081274701CSE009VZ</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>RBC Bag w/Twist Lock, 1000mL</b></p> <p><b>Article number:</b> 00245-00</p> <p><b>Basic UDI-DI:</b> 081274701CSE0010WA</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>Cell Saver Elite Processing Kit (125 mL)</b></p> <p><b>Article number:</b> CSE-P-125</p> <p><b>Basic UDI-DI:</b> 081274701CSE003VM</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Cell Saver Elite Processing Kit (225 mL)</b></p> <p><b>Article number:</b> CSE-P-225</p> <p><b>Basic UDI-DI:</b> 081274701CSE003VM</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Cell Saver Elite Processing Kit (70 mL)</b></p> <p><b>Article number:</b> CSE-P-70</p> <p><b>Basic UDI-DI:</b> 081274701CSE003VM</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<b>Sequestration Kit</b>  <b>Article number:</b> CSE-SQ-1000  <b>Basic UDI-DI:</b> 081274701CSE007VV	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123
<b>CS ELITE FASTPACK, 125mL, 150U</b>  <b>Article number:</b> CSE-FP-125V  <b>Basic UDI-DI:</b> 081274701CSE0011WC	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123
<b>CS ELITE FASTPACK, 225mL, 20U</b>  <b>Article number:</b> CSE-FP-225F  <b>Basic UDI-DI:</b> 081274701CSE0011WC	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>CS ELITE FASTPACK, 225mL, 150U</b></p> <p><b>Article number:</b> CSE-FP-225V</p> <p><b>Basic UDI-DI:</b> 081274701CSE0011WC</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>High Efficiency In-Process Filter System for Leucocyte Removal from Pooled Buffy Coat Platelets</b></p> <p><b>Article number:</b> ATSBC1EB</p> <p><b>Basic UDI-DI:</b> 0887691WB0002S2</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>High Efficiency In-Process Filter System for Leucocyte Removal from Pooled Buffy Coat Platelets</b></p> <p><b>Article number:</b> ATSBC1EE</p> <p><b>Basic UDI-DI:</b> 0887691WB0002S2</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>High Efficiency In-Process Filter System for Leucocyte Removal from Pooled Buffy Coat Platelets</b></p> <p><b>Article number:</b> ATSBC1EPSB</p> <p><b>Basic UDI-DI:</b> 0887691WB0002S2</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>High Efficiency In-Process Filter System for Leucocyte Removal from Pooled Buffy Coat Platelets</b></p> <p><b>Article number:</b> ATSBC1ESB</p> <p><b>Basic UDI-DI:</b> 0887691WB0002S2</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>High Efficiency In-Process Filter System for Leucocyte Removal from Pooled Buffy Coat Platelets</b></p> <p><b>Article number:</b> ATSBC1ESE</p> <p><b>Basic UDI-DI:</b> 0887691WB0002S2</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>ELX Platelet Storage Bag</b></p> <p><b>Article number:</b> NFP1EE</p> <p><b>Basic UDI-DI:</b> 0887691WB0003S4</p>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123
<p><b>RC High Efficiency Leucocyte Removal Filter with Attached Set for Blood Transfusion</b></p> <p><b>Article number:</b> RC1VAE</p> <p><b>Basic UDI-DI:</b> 0887691WB0004S6</p>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123
<p><b>RC High Efficiency Leucocyte Removal Filter with Attached Set for Blood Transfusion</b></p> <p><b>Article number:</b> RC2VAE</p> <p><b>Basic UDI-DI:</b> 0887691WB0004S6</p>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>RN Neonatal High Efficiency Leucocyte Removal Filter for Red Cells</b></p> <p><b>Article number:</b> RN1</p> <p><b>Basic UDI-DI:</b> 0887691WB0005S8</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Cell Saver Elite</b></p> <p><b>Article number:</b> CSE-E-IE</p> <p><b>Basic UDI-DI:</b> 081274701CSE001VH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Cell Saver Elite</b></p> <p><b>Article number:</b> CSE-E-CS</p> <p><b>Basic UDI-DI:</b> 081274701CSE001VH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<b>Cell Saver Elite</b>  <b>Article number:</b> CSE-E-DE  <b>Basic UDI-DI:</b> 081274701CSE001VH	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123
<b>Cell Saver Elite</b>  <b>Article number:</b> CSE-E-ES  <b>Basic UDI-DI:</b> 081274701CSE001VH	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123
<b>Cell Saver Elite</b>  <b>Article number:</b> CSE-E-FR  <b>Basic UDI-DI:</b> 081274701CSE001VH	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<b>Cell Saver Elite</b>  <b>Article number:</b> CSE-E-IT  <b>Basic UDI-DI:</b> 081274701CSE001VH	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123
<b>Cell Saver Elite</b>  <b>Article number:</b> CSE-E-NL  <b>Basic UDI-DI:</b> 081274701CSE001VH	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123
<b>Cell Saver Elite</b>  <b>Article number:</b> CSE-E-NO  <b>Basic UDI-DI:</b> 081274701CSE001VH	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>Cell Saver Elite</b></p> <p><b>Article number:</b> CSE-E-PT</p> <p><b>Basic UDI-DI:</b> 081274701CSE001VH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Cell Saver Elite</b></p> <p><b>Article number:</b> CSE-E-RU</p> <p><b>Basic UDI-DI:</b> 081274701CSE001VH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Cell Saver Elite</b></p> <p><b>Article number:</b> CSE-E-SV</p> <p><b>Basic UDI-DI:</b> 081274701CSE001VH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>Cell Saver Elite</b></p> <p><b>Article number:</b> CSE-E-UK</p> <p><b>Basic UDI-DI:</b> 081274701CSE001VH</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Cell Saver Elite+</b></p> <p><b>Article number:</b> CSE-EW-IE</p> <p><b>Basic UDI-DI:</b> 081274701CSE0012WE</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Cell Saver Elite+</b></p> <p><b>Article number:</b> CSE-EW-CS</p> <p><b>Basic UDI-DI:</b> 081274701CSE0012WE</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<b>Cell Saver Elite+</b>  <b>Article number:</b> CSE-EW-DE  <b>Basic UDI-DI:</b> 081274701CSE0012WE	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123
<b>Cell Saver Elite+</b>  <b>Article number:</b> CSE-EW-ES  <b>Basic UDI-DI:</b> 081274701CSE0012WE	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123
<b>Cell Saver Elite+</b>  <b>Article number:</b> CSE-EW-FR  <b>Basic UDI-DI:</b> 081274701CSE0012WE	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<b>Cell Saver Elite+</b>  <b>Article number:</b> CSE-EW-IT  <b>Basic UDI-DI:</b> 081274701CSE0012WE	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123
<b>Cell Saver Elite+</b>  <b>Article number:</b> CSE-EW-NL  <b>Basic UDI-DI:</b> 081274701CSE0012WE	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123
<b>Cell Saver Elite+</b>  <b>Article number:</b> CSE-EW-NO  <b>Basic UDI-DI:</b> 081274701CSE0012WE	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<b>Cell Saver Elite+</b>  <b>Article number:</b> CSE-EW-PT  <b>Basic UDI-DI:</b> 081274701CSE0012WE	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123
<b>Cell Saver Elite+</b>  <b>Article number:</b> CSE-EW-RU  <b>Basic UDI-DI:</b> 081274701CSE0012WE	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123
<b>Cell Saver Elite+</b>  <b>Article number:</b> CSE-EW-SV  <b>Basic UDI-DI:</b> 081274701CSE0012WE	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>Cell Saver Elite+</b></p> <p><b>Article number:</b> CSE-EW-UK</p> <p><b>Basic UDI-DI:</b> 081274701CSE0012WE</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>High Efficiency Post-Process Filter System for Leucocyte Removal from Red Cells</b></p> <p><b>Article number:</b> BPF4BBS</p> <p><b>Basic UDI-DI:</b> 0887691WB0006SA</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>High Efficiency Post-Process Filter System for Leucocyte Removal from Red Cells</b></p> <p><b>Article number:</b> BPF4NEOL</p> <p><b>Basic UDI-DI:</b> 0887691WB0006SA</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>High Efficiency Post-Process Filter System for Leucocyte Removal from Red Cells</b></p> <p><b>Article number:</b> BPFAPLUS</p> <p><b>Basic UDI-DI:</b> 0887691WB0007SC</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>High Efficiency Post-Process Filter System for Leucocyte Removal from Red Cells</b></p> <p><b>Article number:</b> BPFAPLUSHK</p> <p><b>Basic UDI-DI:</b> 0887691WB0007SC</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>Cryoprecipitate Pooling Set</b></p> <p><b>Article number:</b> CP1BE</p> <p><b>Basic UDI-DI:</b> 0887691WB0011S3</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>PL High Efficiency Leucocyte Removal Filter with Attached Set for Platelet Transfusion</b></p> <p><b>Article number:</b> PL2VAE</p> <p><b>Basic UDI-DI:</b> 0887691WB0008SE</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>PL High Efficiency Leucocyte Removal Filter with Attached Set for Platelet Transfusion</b></p> <p><b>Article number:</b> PL3VAE</p> <p><b>Basic UDI-DI:</b> 0887691WB0008SE</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>RS Leucocyte Removal Filter with Attached Set for Salvaged Blood</b></p> <p><b>Article number:</b> RS1VAE</p> <p><b>Basic UDI-DI:</b> 0887691WB0014S9</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>LipiGuard SB Reinfusion Filter For Salvaged Blood</b></p> <p><b>Article number:</b> SB1E</p> <p><b>Basic UDI-DI:</b> 0887691WB0010RZ</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>
<p><b>PL High Efficiency Leucocyte Removal Filter for Platelets</b></p> <p><b>Article number:</b> PL1BE</p> <p><b>Basic UDI-DI:</b> 0887691WB0009SG</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 105829 0001 Rev. 00 NB# 0123</p>



**Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p><b>SafeTrace Tx®</b></p> <p><b>Article number:</b> SafeTrace Tx</p> <p><b>Basic UDI-DI:</b> 081274701HSS0012P</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p> <p><input type="checkbox"/> Class I reusable surgical instrument</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input type="checkbox"/> Certification as follows:</p> <p>Certificate #1; NB#</p> <p>or</p> <p><input checked="" type="checkbox"/> N/A – Device did not require a Notified Body certificate under Directives</p> <p><b>NOTE:</b> Device was self-declared under MDD (class I) – not covered by the certificate – and is now class IIb under MDR.</p>

**Confirmation Letter Version History**

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-04-30	713278415   PSE200210004483_CL	Initial issue