KONFIDENCIALU

EC CERTIFICATE

for the Quality Assurance System

according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

QualiMed Innovative Medizinprodukte GmbH

KOPIJA TIKRA

Boschstraße 16, 21423 Winsen, Germany

Certified location:

Boschstraße 16, 21423 Winsen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50289-Z7-00, the decision dated 2020-03-19 and is only valid in connection with the successful performance of the annual surveillance audits.
This certificate is only valid in connection with the main certificate no. 50289-16-07.

This certificate is valid from 2020-03-19 to 2024-05-26

Registration No.: 50289-16-07-2

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2020-03-19
Notified Body ID-number: 0124

Annex to the EC Certificate No. 50289-16-07-2

Valid from 2020-03-19 to 2024-05-26

Revision status of the annex: 0 dated 2020-03-19

Devices/device categories included in the certificate:

Brand: TsunaMed

Class II a:

- JUTURNA-vq PTA Balloon Catheter
- JUTURNA-e PTA Balloon Catheter

Class II b:

- NAVALIS Peripheral Vascular Self Expanding Stent System
- NAVALIS-pp Peripheral Vascular Self Expanding Stent System
- LITUS^{Xi} Peripheral Balloon Expandable Stent System
- LITUSXi^{6F} Peripheral Balloon Expandable Stent System
- LITUS^{Xi-} Peripheral Balloon Expandable Stent System

Class III:

- EMAX Aspiration Catheter
- MAGMA Rapamycin-Eluting Coronary Stent System
- JUTURNA-c PTCA Balloon Catheter

For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-03-19
Notified Body ID-number: 0124

KONFIDENCIALU

CE SERTIFIKATAS

DEKRA

Remiantis direktyvos 93/42/EEC Priedu II išskyrus 4 skyrių

kompanija

Qualimed Innovative Medizinprodukte GmbH
Boschstrase 16, 21423 Winsen, Vokietija

atitinka kokybės sistemą medicinos prietaisų, nurodytų direktyvos 93/42/EEC II priede.
Patvirtinimas yra priimtas 2018-04-03 ir rezultatai apibendrinti raporte Nr. 50289-Z6-00.

Šis sertifikatas galioja nuo 2020-03-19 iki 2024-05-26

Registracijos Nr.: 50289-16-07-2

Parašas
Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2020-03-19
Sertifikavimo tarnybos ID numeris: 0124

Vertimas tikras

Priedas prie sertifikato 50289-16-07-2

Galioja nuo 2020-03-19 iki 2024-05-26

Priemonės, nurodytos sertifikate

Prekinis ženklas: TsunaMed

Klasė IIa:

JUTURNA-vq PTA balioniniai kateteriai
JUTURNA-e PTA balioniniai kateteriai

Klasė IIb:
NAVALIS savaime išsiskleidžiantys periferiniai kraujagyslių stentai
NAVALIS-pp savaime išsiskleidžiantys periferiniai kraujagyslių stentai
LITUS^{Xi} periferiniai balionu išplečiami stentai
LITUS$^{Xi\ 6F}$ periferiniai balionu išplečiami stentai
LITUS^{Xi-} periferiniai balionu išplečiami stentai

Klasė III:
EMAX atsiurbimo kateteriai
MAGMA rapamicinu dengti koronariniai stentai
JUTURNA-c PTCA balioniniai kateteriai

Vertimas tikras

Direktorė
Vestina Strakšytė

Parašas
Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2020-03-19
Sertifikavimo tarnybos ID numeris: 0124

QualiMed®
A Q3 Medical Company

QualiMed Innovative Medizinprodukte GmbH
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www.qualimed.de
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21423 Winsen
Germany

Zeichen Your sign	Ihre Nachricht vom Your message of	Unser Zeichen Our sign	Datum Date
		QualiMed MDR_Manufacturer Declaration_240426.docx	26. April 2024

Manufacturer's Declaration

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	QualiMed Innovative Medizinprodukte GmbH
Manufacturer address and contact details	Boschstraße 16, 21423 Winsen Phone: +49 4171 6578 0 Fax: +49 4171 6578 11 E-mail: info@qualimed.de Website: www.qualimed.de
Single Registration Number (SRN) (if available)	DE-MF-000008095

Authorised Representative name (if applicable)	Not applicable
Authorised Representative address and contact details	-
Single Registration Number (SRN) (if available)	-

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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Boschstraße 16
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TO WHOM IT MAY CONCERN,

Notified body name (if applicable)	DEKRA Certification GmbH
Notified body number (if applicable)	0124
Directive Certificate number(s) to which this confirmation is made (if applicable)	See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	See attached schedule
End date of extended validity/transition period	See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

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TO WHOM IT MAY CONCERN,

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
☒ A QMS in accordance with Article 10(9) MDR is in place.
☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: Qualimed Innovative Medizinprodukte GmbH

Location & Date: Winsen (Luhe), 26 April 2024

Signature, Print Name, Title:

Contact Details (at least email):

mguelcher@q3medical.com

Boschstraße 16 · D-21423 Winsen
Telefon + 49 (4171) 6578-0
Telefax + 49 (4171) 657811
e-Mail:qualimed@t-online.de

ppa / CRO

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
PTCA Balloon Catheter (PC)	50289-16-07, Rev 00 50289-23-N5 Rev.02	26/05/2024 30/03/2023	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
PYXIS-c PTCA Balloon Catheter	50289-16-07-1, Rev 00 50289-23-N5-1 Rev.02	26/05/2024 30/03/2023	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
JUTURNA-c PTCA Balloon Catheter	50289-16-07-2, Rev 00 50289-23-N5-2 Rev.02	26/05/2024 30/03/2023	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
PEGASUS PTCA Balloon Catheter	50289-16-07-3, Rev 00 50289-23-N5-3 Rev.02	26/05/2024 30/03/2023	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
ISTAR PTCA Balloon Catheter	50289-16-07-5, Rev 01 50289-23-N5-4 Rev.00	26/05/2024 30/03/2023	DEKRA – 0124	DEKRA – 0124	31/12/2027	-

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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Aspiration Catheter (VX)	50289-16-07, Rev 00 50289-23-Q3 Rev.01	26/05/2024 02/04/2023	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
VMAX Aspiration Catheter	50289-16-07-1, Rev 00 50289-23-Q3-1 Rev.01	26/05/2024 02/04/2023	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
EMAX Aspiration Catheter	50289-16-07-2, Rev 00 50289-23-Q3-2 Rev.01	26/05/2024 02/04/2023	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
POLLUX Aspiration Catheter	50289-16-07-3, Rev 00 50289-23-Q3-3 Rev.01	26/05/2024 02/04/2023	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
ISOLV Aspiration Catheter	50289-16-07-5, Rev 01 50289-23-Q3-5 Rev.00	26/05/2024 02/04/2023	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
Peripheral Balloon Expandable Stent System (QBX)	50289-16-07, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
PROPOS^{XS} Peripheral Balloon Expandable Stent System	50289-16-07-1, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
PROPOS$^{S\ 6F}$ Peripheral Balloon Expandable Stent System	50289-16-07-1, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
LITUS $^{Xi-}$ Peripheral Balloon Expandable Stent System	50289-16-07-2, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
LITUS $^{Xi\ 6F}$ Peripheral Balloon Expandable Stent System	50289-16-07-2, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2027	-

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TALON Minor- Peripheral Balloon Expandable Stent System	50289-16-07-3, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
TALON Minor 6F Peripheral Balloon Expandable Stent System	50289-16-07-3, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
THALIS Flex- Peripheral Stent Implantation System	50289-16-07-5, Rev 01	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
THALIS Flex 6F Peripheral Stent Implantation System	50289-16-07-5, Rev 01	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
PTA Balloon Catheter (PVQ)	50289-16-07, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2028	-
GRAVIS PTA Balloon Catheter	50289-16-07-1, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2028	-
DELPHINUS PTA Balloon Catheter	50289-16-07-1, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2028	-
LATUS PTA Balloon Catheter	50289-16-07-1, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2028	-
FISTULEX PTA Balloon Catheter	50289-16-07-1, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2028	-
JUTURNA-vq PTA Balloon Catheter	50289-16-07-2, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2028	-
PERSEUS-q PTA Balloon Catheter	50289-16-07-3, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2028	-
ALLUNGA PTA Balloon Catheter	50289-16-07-5, Rev 01	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2028	-
Peripheral Vascular Self Expanding Stent System (PS)	50289-16-07, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
Peripheral Vascular Self-Expanding Stent	50289-16-07, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2027	-

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System (PSpp)						
POLARIS Peripheral Vascular Self-Expanding Stent System	50289-16-07-1, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
POLARIS-pp Peripheral Vascular Self-Expanding Stent System	50289-16-07-1, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
NAVALIS Peripheral Vascular Self-Expanding Stent System	50289-16-07-2, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
NAVALIS-pp Peripheral Vascular Self-Expanding Stent System	50289-16-07-2, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
PONTOS Peripheral Vascular Self-Expanding Stent System	50289-16-07-3, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
PONTOS-pp Peripheral Vascular Self-Expanding Stent System	50289-16-07-3, Rev 00	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
FACILE Self-expanding Stent System	50289-16-07-5, Rev 01	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2027	-
FACILE-pp Self-expanding Stent System	50289-16-07-5, Rev 01	26/05/2024	DEKRA – 0124	DEKRA – 0124	31/12/2027	-

DEKRA

DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

QualiMed Innovative Medizinprodukte GmbH
Mr Bhavik Gondaliya
Boschstraße 16
21423 Winsen
Germany

DEKRA Certification GmbH
Handwerkstraße 15
D-70565 Stuttgart

Contact Karin Heckel
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Email karin.heckel@dekra.com

Headquarters
Phone +49.711.7861-2566
Fax +49.711.7861-2615

Date 2023-09-07

Subject: Notified Body Confirmation Letter

Our reference: 50289-CoL-00, Rev. 2

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 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Dear Mr. Gondaliya

This letter confirms that, DEKRA Certification GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0124 on NANDO, hereby confirms that a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer is still pending:

QualiMed Innovative Medizinprodukte GmbH
Boschstraße 16
21423 Winsen
Deutschland

SRN Number: DE-MF-000008095

Furthermore, DEKRA Certification GmbH confirms that an agreement between QualiMed Innovative Medizinprodukte GmbHand DEKRA Certification GmbH is in place about the surveillance of the products that are covered by the certificate(s) mentioned in table 1 according to Regulation (EU) 2017/745 Article 120.

Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulation (EU) 2017/745 as regards the transitional provision for certain medical devices has been published on 20 March 2023 and came into force on the same day. This Regulation 2023/607 has amended MDR 2017/745 to now identify that under certain conditions certificates issued by Notified Bodies, as DEKRA Certification GmbH, in accordance with the MDD 93/42/EEC that were still valid on 26.05.2021 and that have not

been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate, see Table 1 under certain conditions. Additionally, should the QualiMed Innovative Medizinprodukte GmbH intend to make use of the extension of the validity of the EC-certificates, involvement of DEKRA Certification GmbH for continued surveillance is required.

This Confirmation Letter identifies the products or product groups and EC certificates according to MDD 93/42/EEC (see Table 1) for which QualiMed Innovative Medizinprodukte GmbH intends to make use of the option for extension of the validity of the EC certificates (see Table 1).

This Confirmation Letter identifies its validity until the latest: **2024-05-25**.

If QualiMed Innovative Medizinprodukte GmbH has intentions to make use of the option for extension of the validity of the EC certificates (see Table 1) as detailed in the amendment of the MDR 2017/745 by Regulation (EU) 2023/607:

26 May 2026 for Class III custom-made implantable devices
31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - 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 or have a 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 following conditions have to be met:

QualiMed Innovative Medizinprodukte GmbH or it's the Authorized Representative has to ensure that a formal application acc. to the MDR 2017/745 Section 4.3, first subparagraph of Annex VII for the conformity assessment will have been lodged with DEKRA Certification GmbH, latest by 26 May 2024. The application should be placed for the product(s) or groups of products intended to substitute those product(s).
QualiMed Innovative Medizinprodukte GmbH or its Authorized Representative has to ensure that
a written agreement in accordance with the MDR 2017/745 Section 4.3, second subparagraph of Annex VII will have been signed with DEKRA Certification GmbH, latest by 26 September 2024.

Should the MDR application not be lodged and the written agreement not to be signed acc. to the mentioned timelines, the EC certificates mentioned in the Table 1, cannot be considered valid after 26. September 2024.

On behalf of the Notified Body,

Stephanie
07:56:19+02:00

Stephanie Donner
2023/09/07

DEKRA

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Product or product group identification acc. to MDD -certificate	MDD Device classification	MDD Certificate and Certificate Annex No. with revision
PTCA Balloon Catheter (PC)	Class III	50289-16-07, Rev 00; NB: 0124 50289-23-N5 Rev.02; NB: 0124
PYXIS-c PTCA Balloon Catheter	Class III	50289-16-07-1, Rev 00; NB: 0124 50289-23-N5-1 Rev.02; NB: 0124
JUTURNA-c PTCA Balloon Catheter	Class III	50289-16-07-2, Rev 00; NB: 0124 50289-23-N5-2 Rev.02; NB: 0124
PEGASUS PTCA Balloon Catheter	Class III	50289-16-07-3, Rev 00; NB: 0124 50289-23-N5-3 Rev.02; NB: 0124
ISTAR PTCA Balloon Catheter	Class III	50289-16-07-5, Rev 01; NB: 0124 50289-23-N5-4 Rev.00; NB: 0124
Aspiration Catheter (VX)	Class III	50289-16-07, Rev 00; NB: 0124 50289-23-Q3 Rev.01; NB: 0124
VMAX Aspiration Catheter	Class III	50289-16-07-1, Rev 00; NB: 0124 50289-23-Q3-1 Rev.01; NB: 0124
EMAX Aspiration Catheter	Class III	50289-16-07-2, Rev 00; NB: 0124 50289-23-Q3-2 Rev.01; NB: 0124
POLLUX Aspiration Catheter	Class III	50289-16-07-3, Rev 00; NB: 0124 50289-23-Q3-3 Rev.01; NB: 0124
ISOLV Aspiration Catheter	Class III	50289-16-07-5, Rev 01; NB: 0124 50289-23-Q3-5 Rev.00; NB: 0124
Peripheral Balloon Expandable Stent System (QBX)	Class IIb	50289-16-07, Rev 00; NB: 0124
PROPOSX^{S} Peripheral Balloon Expandable Stent System	Class IIb	50289-16-07-1, Rev 00; NB: 0124
PROPOSS ^{6F} Peripheral Balloon Expandable Stent System	Class IIb	50289-16-07-1, Rev 00; NB: 0124
LITUS $^{XI-}$ Peripheral Balloon Expandable Stent System	Class IIb	50289-16-07-2, Rev 00; NB: 0124
LITUS $^{XI\ 6F}$ Peripheral Balloon Expandable Stent System	Class IIb	50289-16-07-2, Rev 00; NB: 0124
TALON $^{Minor-}$ Peripheral Balloon Expandable Stent System	Class IIb	50289-16-07-3, Rev 00; NB: 0124
TALON $^{Minor\ 6F}$ Peripheral Balloon Expandable Stent System	Class IIb	50289-16-07-3, Rev 00; NB: 0124
THALIS $^{Flex-}$ Peripheral Stent Implantation System	Class IIb	50289-16-07-5, Rev 01; NB: 0124
THALIS $^{Flex\ 6F}$ Peripheral Stent Implantation System	Class IIb	50289-16-07-5, Rev 01; NB: 0124
PTA Balloon Catheter (PVQ)	Class IIa	50289-16-07, Rev 00; NB: 0124
GRAVIS PTA Balloon Catheter	Class IIa	50289-16-07-1, Rev 00; NB: 0124

Product or product group identification acc. to MDD -certificate	MDD Device classification	MDD Certificate and Certificate Annex No. with revision
DELPHINUS PTA Balloon Catheter	Class IIa	50289-16-07-1, Rev 00; NB: 0124
LATUS PTA Balloon Catheter	Class IIa	50289-16-07-1, Rev 00; NB: 0124
FISTULEX PTA Balloon Catheter	Class IIa	50289-16-07-1, Rev 00; NB: 0124
JUTURNA-vq PTA Balloon Catheter	Class IIa	50289-16-07-2, Rev 00; NB: 0124
PERSEUS-q PTA Balloon Catheter	Class IIa	50289-16-07-3, Rev 00; NB: 0124
ALLUNGA PTA Balloon Catheter	Class IIa	50289-16-07-5, Rev 01; NB: 0124
Peripheral Vascular Self Expanding Stent System (PS)	Class IIb	50289-16-07, Rev 00; NB: 0124
Peripheral Vascular Self-Expanding Stent System (PSpp)	Class IIb	50289-16-07, Rev 00; NB: 0124
POLARIS Peripheral Vascular Self-Expanding Stent System	Class IIb	50289-16-07-1, Rev 00; NB: 0124
POLARIS-pp Peripheral Vascular Self-Expanding Stent System	Class IIb	50289-16-07-1, Rev 00; NB: 0124
NAVALIS Peripheral Vascular Self-Expanding Stent System	Class IIb	50289-16-07-2, Rev 00; NB: 0124
NAVALIS-pp Peripheral Vascular Self-Expanding Stent System	Class IIb	50289-16-07-2, Rev 00; NB: 0124
PONTOS Peripheral Vascular Self-Expanding Stent System	Class IIb	50289-16-07-3, Rev 00; NB: 0124
PONTOS-pp Peripheral Vascular Self-Expanding Stent System	Class IIb	50289-16-07-3, Rev 00; NB: 0124
FACILE Self-expanding Stent System	Class IIb	50289-16-07-5, Rev 01; NB: 0124
FACILE-pp Self-expanding Stent System	Class IIb	50289-16-07-5, Rev 01; NB: 0124