

Integra LifeSciences (Ireland) Ltd,
IDA Business & Technology Park,
Sragh,
Tullamore,
County Offaly,
Ireland

23 April 2024

Notified Body Confirmation Letter

Reference: **EU2023-607/843569**

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 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has 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 following manufacturer:

Integra LifeSciences (Ireland) Ltd,
IDA Business & Technology Park,
Sragh,
Tullamore,
County Offaly,
Ireland

SRN Number (if available): IE-MF-000003849

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 the NB is also responsible for appropriate surveillance of the

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Validity of this letter may be verified by writing to Certificate.Verification@bsigroup.com

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 the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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, by the 20 Mar 2023 for the relevant devices.

The transition timelines 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 (as amended by (EU) 2023/607), 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 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)

On behalf of BSI Group The Netherlands B.V.,

[Redacted Signature]
Senior Vice President, Medical Devices

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:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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>Cusa Excel and Cusa Clarity Tips and Flues</p> <table border="1" data-bbox="113 734 312 1731"> <tr><td>C4600S</td></tr> <tr><td>C4601S</td></tr> <tr><td>C4602S</td></tr> <tr><td>C4603S</td></tr> <tr><td>C4605S</td></tr> <tr><td>C4606S</td></tr> <tr><td>C4607S</td></tr> <tr><td>C4608S</td></tr> <tr><td>C4609S</td></tr> <tr><td>C4610S</td></tr> <tr><td>C4611S</td></tr> <tr><td>C4612S</td></tr> <tr><td>C4613S</td></tr> <tr><td>C4614S</td></tr> <tr><td>C4615S</td></tr> <tr><td>C4616S</td></tr> <tr><td>C4617S</td></tr> <tr><td>C4617SEA</td></tr> <tr><td>C4601ELT</td></tr> <tr><td>C4604ELT</td></tr> <tr><td>C4605ELT</td></tr> <tr><td>C4608ELT</td></tr> <tr><td>C4611ELT</td></tr> <tr><td>C4614ELT</td></tr> </table> <table border="1" data-bbox="113 1794 357 1827"> <tr><td>C7411S</td></tr> </table>	C4600S	C4601S	C4602S	C4603S	C4605S	C4606S	C4607S	C4608S	C4609S	C4610S	C4611S	C4612S	C4613S	C4614S	C4615S	C4616S	C4617S	C4617SEA	C4601ELT	C4604ELT	C4605ELT	C4608ELT	C4611ELT	C4614ELT	C7411S	Class III	N/A	CE 512756 NB 2797 CE 559055 NB 2797
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CUSA Excel Ultrasonic Surgical Aspirator System	Class IIb excluding Class IIb implantable non-WET	N/A	CE 512756 NB 2797										
CUSA Excel Handpiece	Class IIb excluding Class IIb implantable non-WET	N/A	CE 512756 NB 2797										
Cusa Excel CEM Nosecone	Class IIa	N/A	CE 512756 NB 2797										
Cusa Excel manifold tubing	Class IIa	N/A	CE 512756 NB 2797										

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Cusa Excel Torque Wrench	Class I device placed on the market in sterile condition	N/A	CE 512756 NB 2797
CUSA Clarity Ultrasonic Surgical Aspirator system	Class IIb excluding Class IIb implantable non-WET	N/A	CE 512756 NB 2797
CUSA Clarity Handpiece	Class IIb excluding Class IIb implantable non-WET	N/A	CE 512756 NB 2797
CUSA Clarity CEM Nosecone	Class IIa	N/A	CE 512756 NB 2797
Cusa Clarity Quick Connect Cartridge and Tubing Set	Class IIa	N/A	CE 512756 NB 2797
Cusa Clarity Torque Wrench	Class I device placed on the market in sterile condition	N/A	CE 512756 NB 2797
Licox PtO2 Monitor	Class IIb excluding Class IIb implantable non-WET	N/A	CE 512756 NB 2797

Table 2: Devices covered by this letter and for which the NB 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 at the pre-application stage)	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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2024/04/23	Initial issue

MB2797

