Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Westmeath
Ireland

25-Mar-2024

Notified Body Confirmation Letter
Reference: EU2023-607/660790

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:

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SRN Number: IE-MF-000015868

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

Graeme Tunbridge
Senior Vice President, Medical Devices

NB 2797

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
Rusch PercuTwist Set 08019020000000000000268L4	Class IIb excluding Class IIb implantable non-WET	N/A	CE 540595, NB # 2797
Rusch PercuQuick Tracheostomy Tube Set PDT 08019020000000000000268L4	Class IIb excluding Class IIb implantable non-WET	N/A	CE 540595, NB # 2797
Rusch PercuTwist Solo Set 08019020000000000000270KP	Class IIa	N/A	CE 540595, NB # 2797
Ureteral Stents 08019020000000000000240KE	Class IIb implantable non-WET	N/A	CE 540595, NB # 2797
Superglide Ureteral Stent 08019020000000000000240KE	Class IIb implantable non-WET	N/A	CE 540595, NB # 2797
Ureteral Stents for Children 08019020000000000000240KE	Class IIb implantable non-WET	N/A	CE 540595, NB # 2797
Special Ureteral Stents 08019020000000000000240KE	Class IIb implantable non-WET	N/A	CE 540595, NB # 2797
Rigid Ureteral Stents 08019020000000000000240KE	Class IIb implantable non-WET	N/A	CE 540595, NB # 2797
ECO Ureteral Stents 08019020000000000000240KE	Class IIb implantable non-WET	N/A	CE 540595, NB # 2797
Ureter Stent Set, 1 pigtail 08019020000000000000241KG	Class IIa	N/A	CE 540595, NB # 2797
Rectal/Pharyngeal Temperature Sensor 08019020000000000000190KQ	Class IIa	N/A	CE 540595, NB # 2797
Rusch CrystalClear Plus 08019020000000000000150KC	Class IIb excluding Class IIb implantable non-WET	N/A	CE 540595, NB # 2797
Rusch CrystalClear Plus Inner Cannula 08019020000000000000149KT	Class IIb excluding Class IIb implantable non-WET	N/A	CE 540595, NB # 2797

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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
CrystalClear Plus Accessories 08019020000000000000148KR	Class I device placed on the market in sterile condition	N/A	CE 540596, NB # 2797
CrystalClear Plus Sealing Cap 08019020000000000000148KR	Class I device placed on the market in sterile condition	N/A	CE 540596, NB # 2797
Rusch CrystalClear Plus PDT 08019020000000000000263KS	Class IIb excluding Class IIb implantable non-WET	N/A	CE 540595, NB # 2797
Rüsch TracFlex Plus Tracheostomy Tube 08019020000000000000146KM	Class IIb excluding Class IIb implantable non-WET	N/A	CE 540595, NB # 2797
TracFlex Plus Accessories 08019020000000000000144KH	Class I device placed on the market in sterile condition	N/A	CE 540596, NB # 2797
TracFlex Plus Sealing Cap 08019020000000000000144KH	Class I device placed on the market in sterile condition	N/A	CE 540596, NB # 2797
Rusch TracFlex Plus Inner Cannula 08019020000000000000145KK	Class IIb excluding Class IIb implantable non-WET	N/A	CE 540595, NB # 2797
Rusch TracFlex Plus PDT 08019020000000000000269L6	Class IIb excluding Class IIb implantable non-WET	N/A	CE 540595, NB # 2797
Percutaneous Nephrostomy Catheter 08019020000000000000252KM	Class IIa	N/A	CE 540595, NB # 2797
Transurethral Catheters 08019020000000000000254KR	Class IIa	N/A	CE 540595, NB # 2797
Ureter Catheter 08019020000000000000253KP	Class IIa	N/A	CE 540595, NB # 2797
Kidney Stone Extractor 08019020000000000000118KG	Class IIa	N/A	CE 540595, NB # 2797
Rusch CrystalClear Tracheostomy Tube Set PDT 08019020000000000000263KS	Class IIb excluding Class IIb implantable non-WET	N/A	CE 540595, NB # 2797
Rusch TracheoFix 08019020000000000000153KJ	Class IIb excluding Class IIb implantable non-WET	N/A	CE 540595, NB # 2797

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
Rusch Tracheofix Inner Cannula 08019020000000000000151KE	Class IIb excluding Class IIb implantable non-WET	N/A	CE 540595, NB # 2797
Tracheofix Sealing Cap and Fixation Ring 08019020000000000000152KG	Class I device placed on the market in sterile condition	N/A	CE 540596, NB # 2797
TracheoFix Accessories 08019020000000000000152KG	Class I device placed on the market in sterile condition	N/A	CE 540596, NB # 2797
Rusch TracheoFix Tracheostomy Tube Set PDT 08019020000000000000268L4	Class IIb excluding Class IIb implantable non-WET	N/A	CE 540595, NB # 2797
MemoBag Self-Opening Specimen Retrieval Bag 08019020000000000000262KQ	Class IIa	N/A	CE 540595, NB # 2797
Bronchial Tubes (BronchoPart & TracheoPart) 08019020000000000000274KX	Class IIa	N/A	CE 540595, NB # 2797
Breathing Circuits (Sterile & Non-Sterile) 08019020000000000000283KY	Class IIa	N/A	CE 540595, NB # 2797
Fast1 Sternal Intraosseous Device 08019020000000000000284L2	Class IIa	N/A	CE 540596, NB # 2797
EZ-IO Stabilizer Dressing 08019020000000000000116KC	Class I device placed on the market in sterile condition	N/A	CE 540596, NB # 2797
EZ-IO Needles 08019020000000000000115KA	Class IIa	N/A	CE 540596, NB # 2797
EZ-IO Driver 08019020000000000000117KE	Class IIa	N/A	CE 540596, NB # 2797
EZ-Blocker 08019020000000000000256KV	Class IIa	N/A	CE 540595, NB # 2797
Laryngeal Masks 08019020000000000000212K9 (LMA Classic) 08019020000000000000100JV (LMA ProSeal) 08019020000000000000138KN (LMA Fastrach) 08019020000000000000099L5 (LMA Fastrach ETT)	Class IIa	N/A	CE 540595, NB # 2797

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
08019020000000000000139KQ (LMA Fastrach Single Use) 08019020000000000000140K9 (LMA Flexible) 08019020000000000000141KB (LMA Flexible Single Use) 08019020000000000000213KB (LMA Supreme) 08019020000000000000102JZ (LMA Gastro)			

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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
Rusch CrystalClear Plus 08019020000000000000150KC	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # 50076-16-08 NB # 0124

Confirmation Letter Revision History

Date	Action
2023/10/26	Initial issue
2024/03/25	Addition of Memobag Self-Opening Specimen Retrieval Bag, Bronchial Tubes (BronchoPart & TracheoPart), Breathing Circuits (Sterile & Non-Sterile), Fast1 Sternal Intraosseous Device, EZ-IO Stabilizer Dressing, EZ-IO Needles, EZ-IO Driver, EZ-Blocker, Laryngeal Masks to the list

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