Maillefer Instruments Holding Sàrl
Chemin du Verger 3
Ballaigues
CH-1338
Switzerland

2023-07-25

Notified Body Confirmation Letter

Reference: EU2023-607/642164

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:

Maillefer Instruments Holding Sàrl
Chemin du Verger 3
Ballaigues
CH-1338
Switzerland

SRN: CH-MF-000016301

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

Digitally signed by Wendy Xia
Date: 2023.07.25 18:27:46 +01'00'

Wendy Xia

BSI Scheme Manager

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
Aryane-Z	Class IIa	N/A	CE 670383, BSI 2797
CF	Class IIa	N/A	CE 670383, BSI 2797
Day-Z	Class IIa	N/A	CE 670383, BSI 2797
DC	Class IIa	N/A	CE 670383, BSI 2797
Endo-Z	Class IIa	N/A	CE 670383, BSI 2797
EXCAVABUR®	Class IIa	N/A	CE 670383, BSI 2797
LN	Class IIa	N/A	CE 670383, BSI 2797
TC Amalgam Burs	Class IIa	N/A	CE 670383, BSI 2797
TC cavity Burs Round	Class IIa	N/A	CE 670383, BSI 2797
TC cavity burs cone round	Class IIa	N/A	CE 670383, BSI 2797
TC cavity burs cone square	Class IIa	N/A	CE 670383, BSI 2797
TC cavity Burs Cylinder Round	Class IIa	N/A	CE 670383, BSI 2797
TC cavity Burs Cylinder Square	Class IIa	N/A	CE 670383, BSI 2797
TC cavity burs inverted cone	Class IIa	N/A	CE 670383, BSI 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
TRANSMETAL	Class IIa	N/A	CE 670383, BSI 2797
Zekrya®	Class IIa	N/A	CE 670383, BSI 2797
DIAMENDO	Class IIa	N/A	CE 670383, BSI 2797
Diamond Burs	Class IIa	N/A	CE 670383, BSI 2797
ENDO ACCESS BUR	Class IIa	N/A	CE 670383, BSI 2797
Gingival curettage cutters	Class IIa	N/A	CE 670383, BSI 2797
Isometrix burs	Class IIa	N/A	CE 670383, BSI 2797
POST SPACE BUR	Class IIa	N/A	CE 670383, BSI 2797
EASYPOST™ Presicion drill	Class IIa	N/A	CE 670383, BSI 2797
RADIX-ANKER-LONG	Class IIa	N/A	CE 670383, BSI 2797
RADIX-ANKER-STANDARD	Class IIa	N/A	CE 670383, BSI 2797
RS RADIX Penetration Drill	Class IIa	N/A	CE 670383, BSI 2797
RS RADIX Precision Spiral Drill	Class IIa	N/A	CE 670383, BSI 2797
UNIMETRIC Special Precalibrating Drill	Class IIa	N/A	CE 670383, BSI 2797
UNIMETRIC 0.8 MM Special calibration drill	Class IIa	N/A	CE 670383, BSI 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
UNIMETRIC 0.8 MM Special penetration drill	Class IIa	N/A	CE 670383, BSI 2797
UNIMETRIC 1 MM Special calibration drill	Class IIa	N/A	CE 670383, BSI 2797
UNIMETRIC 1 MM Special Penetration Drill	Class IIa	N/A	CE 670383, BSI 2797
GATES glidden drill	Class IIa	N/A	CE 670383, BSI 2797
GATES Sterile Glidden drill	Class IIa	N/A	CE 670383, BSI 2797
LARGO® Peeso Reamer	Class IIa	N/A	CE 670383, BSI 2797
LARGO® Sterile Peeso Reamer	Class IIa	N/A	CE 670383, BSI 2797
Root canal drill	Class IIa	N/A	CE 670383, BSI 2797
Glyde Doses Pack	Class IIa	N/A	CE 670383, BSI 2797
Glyde File Prep™ Intro Package	Class IIa	N/A	CE 670383, BSI 2797
Glyde File Prep™ Syringe Kit	Class IIa	N/A	CE 670383, BSI 2797
Glyde File Prep™ Syringe Tips	Class IIa	N/A	CE 670383, BSI 2797
Protaper® Universal Gutta-Percha Points	Class IIa	N/A	CE 670383, BSI 2797
Gutta-Percha Auxiliary	Class IIa	N/A	CE 670383, BSI 2797
Gutta-Percha ISO Color-Coded .02	Class IIa	N/A	CE 670383, BSI 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
Gutta-Percha ISO Color-Coded 0.4	Class IIa	N/A	CE 670383, BSI 2797
Gutta-Percha ISO Color-Coded 0.6	Class IIa	N/A	CE 670383, BSI 2797
Gutta-Percha ISO Pink .02	Class IIa	N/A	CE 670383, BSI 2797
Gutta-Percha ISO White .02	Class IIa	N/A	CE 670383, BSI 2797
GUTTA-CONDENSOR	Class IIa	N/A	CE 670383, BSI 2797
GUTTA-CONDENSOR STERILE	Class IIa	N/A	CE 670383, BSI 2797
LENTULO® Paste carrier	Class IIa	N/A	CE 670383, BSI 2797
ProTaper® Universal Obturators	Class IIa	N/A	CE 670383, BSI 2797
Thermafil® Obturators	Class IIa	N/A	CE 670383, BSI 2797
Thermafil® Obturators Assorted Anterior Kit	Class IIa	N/A	CE 670383, BSI 2797
Thermafil® Obturators Assorted Posterior Kit	Class IIa	N/A	CE 670383, BSI 2797
EasyPost™ Kit Ø 0.8 mm	Class IIa	N/A	CE 670383, BSI 2797
EasyPost™ Kit Ø 1 mm	Class IIa	N/A	CE 670383, BSI 2797
EasyPost™ Kit Ø 1.3 mm	Class IIa	N/A	CE 670383, BSI 2797
Radix-Anker® Long Integral Set	Class IIa	N/A	CE 670383, BSI 2797
Radix-Anker® Long Set	Class IIa	N/A	CE 670383, BSI 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
Radix-Anker® Standard Demo Set	Class IIa	N/A	CE 670383, BSI 2797
Radix-Anker® Standard Integral Kit	Class IIa	N/A	CE 670383, BSI 2797
Radix-Anker® Standard Integral Set	Class IIa	N/A	CE 670383, BSI 2797
Radix-Anker® Standard Set	Class IIa	N/A	CE 670383, BSI 2797
RS RADIX-STIFTE Integral Set	Class IIa	N/A	CE 670383, BSI 2797
RS RADIX-STIFTE Set	Class IIa	N/A	CE 670383, BSI 2797
Uniclip 0.8mm Set	Class IIa	N/A	CE 670383, BSI 2797
Uniclip 1mm Set	Class IIa	N/A	CE 670383, BSI 2797
Unimetric 0.8mm Integral Set	Class IIa	N/A	CE 670383, BSI 2797
Unimetric 0.8mm Set	Class IIa	N/A	CE 670383, BSI 2797
Unimetric 1mm Integral Set	Class IIa	N/A	CE 670383, BSI 2797
Unimetric 1mm Set	Class IIa	N/A	CE 670383, BSI 2797
Unimetric T Demo Kit	Class IIa	N/A	CE 670383, BSI 2797
EasyPost™	Class IIa	N/A	CE 670383, BSI 2797
X-Post™	Class IIa	N/A	CE 670383, BSI 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
RADIX-ANKER®-STANDARD	Class IIa	N/A	CE 670383, BSI 2797
RADIX-ANKER®-LONG	Class IIa	N/A	CE 670383, BSI 2797
RADIX-ANKER-STANDARD®	Class IIa	N/A	CE 670383, BSI 2797
RS RADIX	Class IIa	N/A	CE 670383, BSI 2797
UNIMETRIC X.X MM	Class IIa	N/A	CE 670383, BSI 2797
ProRinse®	Class IIa	N/A	CE 670383, BSI 2797
START-X® Compatible EMS	Class IIa	N/A	CE 670383, BSI 2797
START-X® Compatible SATELEC	Class IIa	N/A	CE 670383, BSI 2797
START-X® Trial Kit Compatible EMS	Class IIa	N/A	CE 670383, BSI 2797
START-X® Trial Kit Compatible SATELEC	Class IIa	N/A	CE 670383, BSI 2797
THERMA-CUT®	Class IIa	N/A	CE 670383, BSI 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
2023/07/25	Initial issue