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By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 741027 R000

Manufacturer: Maillefer Instruments Holding Sàrl

Address:
Chemin du Verger 3
Ballaigues
CH-1338
Switzerland

Single Registration Number: CH-MF-000016301

EU Authorised Representative: DENTSPLY Detrey GmbH

Address:
De-Trey-Strasse 1
Konstanz
78467
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2022-08-17**

Current Issue Date: **2024-11-25**

Starting Validity Date: **2024-11-25**

Expiry Date: **2027-08-16**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Dental Device Canal Filling and Accessories	Class IIa, Implantable
Devices for Conservative Dentistry and Endodontics	Class IIa
Odontostomatology Instruments	Class IIa
Reusable instruments 'Odontostomatology Instruments'	Class Ir
Reusable and Sterile instruments 'Odontostomatology Instruments'	Class Ir, Class Is

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing, and maintaining sterile conditions.
For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-08-17	3338993	Issued
2023-10-05	3915257	Amended - Addition of subcontractors for dental device canal filling and accessories group. Supplemented - Addition of device group of dental device canal filling and accessories.
Current	30187367	Supplemented - Addition of device group of Devices for Conservative Dentistry and Endodontics.

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