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 and Class IIb implantable devices an 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 Medical Devices

First Issued: **2022-08-17** Date: **2022-08-17** Expiry Date: **2027-08-16**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
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
Current	3338993	Issued

First Issued: **2022-08-17** Date: **2022-08-17** Expiry Date: **2027-08-16**

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

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 741027 R000

Date: **2022-08-17**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Beijing Hongyisifang Radiation Technology Co., Ltd. No. 18 GuangLi Street Tongzhou Industry Park 101113 Beijing People's Republic of China	**Radiation (Gamma Sterilization)**
Dentsply Dental (Tianjin) Co., Ltd. H2 Hongtai Industrial Estate No. 78 Taihua Road TEDA Tianjin 300457 China	**Manufacture**
Dentsply LLC also dba Dentsply Caulk 38 W. Clarke Avenue Milford Delaware 19663 USA	**Manufacture**
Maillefer Instruments Holding Sarl Chemin de Beau - Site 5 Baillagues CH-1338 Switzerland	**Manufacture**

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

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 741027 R000

Date: **2022-08-17**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Synergy Health Allershausen GmbH Kesselbodenstrasse 7 Allershausen D-85391 Germany	**Radiation (Gamma Sterilization)**
Synergy Health Daniken AG Hogenweidstrasse 6 Däniken CH-4658 Switzerland	**Radiation (Gamma Sterilization)**
VDW GmbH Bayerwaldstrasse 15 Munchen 81737 Germany	**Manufacture**

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