

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.****CE 670383**

Issued To:

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

In respect of:

**Design, development and manufacture of sterile and non-sterile dental instruments, motors and contra angles, dental reconstruction systems, dental devices for diagnosis, solutions for irrigation and cleaning of root canals, products for root canal obturation, sterile paperpoints. Those aspects of Annex II relating to securing and maintaining sterility in the manufacture of reamers and files and related to the accuracy of metrology of endodontic software with measuring function.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-05-24**Date: **2021-02-19**Expiry Date: **2023-07-08**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 670383**  
Date: **2021-02-19**  
Issued To: **Maillefer Instruments Holding Sàrl**  
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**Ballaigues**  
**CH-1338**  
**Switzerland**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Advanced Technology Research (A.T.R.) Srl Via San Donato, 1 Pistoia 51100 Italy	<b>Assembly</b>
Dentsply Dental (Tianjin) Co., Ltd. H2 Hongtai Industrial Estate No. 78 Taihua Road TEDA Tianjin 300457 China	<b>Manufacture</b>
DENTSPLY Detrey GmbH De-Trey-Strasse 1 Konstanz 78467 Germany	<b>EU Representative</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Dentsply Indústria e Comércio Ltda. Rua José Francisco de Souza 1926, Distrito Industrial Pirassununga São Paulo 13633-412 Brasil	<b>Manufacture</b>
Dentsply LLC 38W. Clarke Avenue Milford Delaware 19663 USA	<b>Manufacture</b>
DENTSPLY Tulsa Dental Specialties 608 Rolling Hills Drive Johnson City Tennessee 37604 USA	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
ENICS Schweiz AG Austrasse 5300 Turgi Switzerland	<b>Manufacture</b>
FORUM Engineering Technologies (96), Ltd. 40 Hutzot Hayotzer St. P.O Box 3095 Ashkelon 7878563 Israel	<b>Manufacture</b>
M.D.T. Micro Diamond Technologies Ltd. 2 Hamal Street, P.O. Box 1063 Industrial Park North Afula 1857107 Israel	<b>Control of Sterilization</b> <b>Manufacture</b> <b>Packaging</b>

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**CH-1338**  
**Switzerland**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Maillefer Instruments Holding Sarl Chemin de Beau - Site 5 Baillagues CH-1338 Switzerland	<b>Manufacture</b>
NSK Nakanishi 700 Shimohinata Kanuma Tochigi 322-8666 Japan	<b>Manufacture</b>
Sor-van Radiation Ltd. Kiryat Soreq POB 214 Yavne 8180000 Israel	<b>Radiation (Gamma Sterilization)</b>

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**CH-1338**  
**Switzerland**

**Subcontractor:**

**Service(s) supplied**

Synergy Health Daniken AG  
Hogenweidstrasse 6  
Daniken  
CH-4658  
Switzerland

**Radiation (Gamma Sterilization)**

VDW  
Vereinigte Dentalwerke GmbH  
Bayerwaldstrasse 15  
München  
81737  
Germany

**Manufacture**

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## Certificate History

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Date	Reference Number	Action
24 May 2017	8707246	First issue. Transfer from another Notified Body.
06 July 2018	8923290	Certificate Renewal. Removal of 'non-sterile paperpoints' from scope.
19 February 2019	8963068	Traceable to NB 0086.
08 January 2020	3061958	Addition of subcontractors: M.D.T. Micro Diamond Technologies Ltd. ENICS Schweiz AG FORUM Engineering Technologies (96), Ltd. Dentsply Dental (Tianjin) Co., Ltd. Dentsply Indústria e Comércio Ltda Sor-Van Radiation Ltd. Removal of subcontractor: Maillefer Instruments Holding Sarl Le Creux
Current	3369178	eIFU Review completed (sampled eIFU "General Processing Instructions for Endodontic Products" (printed version) for ENDODONTIC FILES, BARBED BROACHES, PROBES, EXCAVATORS, PLUGGERS, SPREADERS, CONDENSORS, DRILLS, BURS, ULTASONIC TIPS, FILLING MATERIALS, PINS & POSTS, WORKING LENGTH TOOLS, OBTURATOR DIAMETER TOOLS) per the requirements of eIFU Regulation 207/2012.

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Date	Reference Number	Action
<b>Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3</b>		
13 September 2021	3506075	Added EC REP 'Dentsply Detrey GmbH'

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

13 September 2021

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

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26<sup>th</sup> May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

<b>Certificate</b>	<b>Directive and Annex</b>	<b>Reference Number</b>	<b>Changes approved</b>
CE 670383	93/42/EEC Annex II, Sec 3.2	3506075	Added EC REP 'Dentsply Detrey GmbH'

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



Gary Slack  
Senior Vice President, Medical Devices