

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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List of Significant Subcontractors

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

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Date: **2021-02-19**
Issued To: **Maillefer Instruments Holding Sàrl**
Chemin du Verger 3
Ballaigues
CH-1338
Switzerland

Subcontractor:	Service(s) supplied
Advanced Technology Research (A.T.R.) Srl Via San Donato, 1 Pistoia 51100 Italy	Assembly
Dentsply Dental (Tianjin) Co., Ltd. H2 Hongtai Industrial Estate No. 78 Taihua Road TEDA Tianjin 300457 China	Manufacture
Dentsply Indústria e Comércio Ltda. Rua José Francisco de Souza 1926, Distrito Industrial Pirassununga São Paulo 13633-412 Brasil	Manufacture

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Switzerland

Subcontractor:	Service(s) supplied
Dentsply LLC 38W. Clarke Avenue Milford Delaware 19663 USA	Manufacture
DENTSPLY Tulsa Dental Specialties 608 Rolling Hills Drive Johnson City Tennessee 37604 USA	Manufacture
ENICS Schweiz AG Austrasse 5300 Turgi Switzerland	Manufacture

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Switzerland

Subcontractor:	Service(s) supplied
FORUM Engineering Technologies (96), Ltd. 40 Hutzot Hayotzer St. P.O Box 3095 Ashkelon 7878563 Israel	Manufacture
M.D.T. Micro Diamond Technologies Ltd. 2 Hamal Street, P.O. Box 1063 Industrial Park North Afula 1857107 Israel	Control of Sterilization Manufacture Packaging
Maillefer Instruments Holding Sarl Chemin de Beau - Site 5 Baillagues CH-1338 Switzerland	Manufacture

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Ballaigues
CH-1338
Switzerland

Subcontractor:	Service(s) supplied
NSK Nakanishi 700 Shimohinata Kanuma Tochigi 322-8666 Japan	Manufacture
Sor-van Radiation Ltd. Kiryat Soreq POB 214 Yavne 8180000 Israel	Radiation (Gamma Sterilization)
Synergy Health Daniken AG Hogenweidstrasse 6 Daniken CH-4658 Switzerland	Radiation (Gamma Sterilization)

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Ballaigues
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Subcontractor:

Service(s) supplied

VDW
Vereinigte Dentalwerke GmbH
Bayerwaldstrasse 15
München
81737
Germany

Manufacture

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 670383**
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Ballaigues
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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.