

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:

Certificate No: **CE 670383**
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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Ballaigues
CH-1338
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
CH-1338
Switzerland

Subcontractor:

Service(s) supplied

VDW
 Vereinigte Dentalwerke GmbH
 Bayerwaldstrasse 15
 München
 81737
 Germany

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Certificate History

Certificate No: **CE 670383**
Date: **2021-02-19**
Issued To: **Maillefer Instruments Holding Sàrl**
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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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This certificate was issued electronically and is bound by the conditions of the contract.

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.