

EC Certificate - Full Quality Assurance System

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

No.**CE 670383**

Issued To:

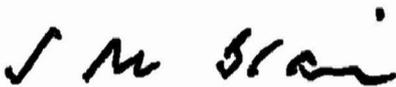
**Maillefer Instruments Holding Sàrl
Chemin du Verger 3
Ballaigues
CH-1338
Switzerland**

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 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2017-05-24**Date: **2018-07-06**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.