



EC-CERTIFICATE

(Production quality assurance)



This is to certify that the company

DFS-DIAMON GmbH

Ländenstr. 1
93339 Riedenburg
Germany

has implemented and maintains a quality assurance system which applies to the manufacture and final controls of the products.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex V of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Rotary Dental Instruments and Dental materials and Attachments as listed in the annex.

The manufacturer is subject to surveillance according to Annex V, Section 4. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	301394 MR5
Certificate unique ID	170765128
Effective date	2020-05-03
Expiry date	2024-05-26
Frankfurt am Main	2020-05-03

DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



Annex to certificate
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Device family	Device	Class
Rotary Dental Instruments	Rotary dental diamond instruments and carbide instruments	Ila
	Uporal-polishers	Ila
	Diafix-Oral polishers	Ila
	Bone Cutters	Ila
	Tissue Punch	Ila
	Dental polishers	Ila
	Soft Tissue Trimmer PreciCut	Ila
Dental materials	Dental alloys and joining materials	Ila
Attachments	Precision Matrice, PEEK	Ila