



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

Bernhard Förster GmbH

Westliche Karl-Friedrich-Straße 151
75172 Pforzheim
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

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

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Orthodontic products according to annex

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this 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.	055387 MR2
Certificate unique ID	170731106
Effective date	2018-12-13
Expiry date	2023-12-12
Frankfurt am Main	2018-12-13

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
Screws	Palatal split screws	IIa
Wires	Wires, arch wires and preformed wires	IIa
Wires with force transmission	Preformed wires and wire parts with spring function	IIa
Attachments	Brackets and buccal tubes and accessories	IIa
Bands	Molar bands with and without welded attachments	IIa
Accessories	Elastics for ligation, rotation and force transmission to teeth	IIa
Implants	Screws for orthodontic anchorage	IIb