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	170774634
Effective date	2021-03-12
Expiry date	2023-12-12
Frankfurt am Main	2021-03-12

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

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

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 055387 MR2
Certificate unique ID: 170774634
Effective date: 2021-03-12

Bernhard Förster GmbH

Westliche Karl-Friedrich-Straße 151
75172 Pforzheim
Germany

Device family	Device	Class
Screws	Expansion- and palatal split screws and accessories	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
Orthodontic plastic devices and auxillaries	Orthodontic plastic materials and auxiliaries	IIa
	Plastic appliances for orthodontic treatment	IIa

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Bernhard Förster GmbH · Postfach 660 · 75106 Pforzheim (Germany)

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Bernhard Förster GmbH
Manufacturer address and contact details	Westliche Karl-Friedrich-Straße 151, 75172 Pforzheim (Tel: +49 7231 459-0, Fax: +49 7231 459-102)
Single Registration Number (SRN) (if available)	DE-MF-000006256

Authorised Representative name (if applicable)	-
Authorised Representative address and contact details	-
Single Registration Number (SRN) (if available)	-

Notified body name (if applicable)	☒ See attached schedule
Notified body number (if applicable)	☒ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☒ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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Filiale Pforzheim
BIC: DEUTDESM666
IBAN: DE83 6667 0006 0017 1058 00

Baden-Württembergische Bank
Stuttgart
BIC: SOLADEST600
IBAN: DE81 6005 0101 7498 5004 69

Sparkasse
Pforzheim Calw
BIC: PZHSDE66XXX
IBAN: DE48 6665 0085 0000 8063 74

Postbank
Karlsruhe
BIC: PBNKDEFF600
IBAN: DE12 6601 0075 0147 8417 58

Geschäftsführer:
Stefan Förster (Sprecher)
Bernhard Förster

Registergericht Mannheim HRB 500987

Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☒ See attached schedule
End date of extended validity/transition period	☒ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☒ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

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Signed for and on behalf of the manufacturer:

Full Company Name	Bernhard Förster GmbH
Location & Date	November 13th, 2023
Signature, Print Name, Title	Stefan Förster Managing Director (CEO)
Contact Details (at least email)	Michael.fiess@forestadent.com

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Headgears & Traction Bands	**Cert. Reg. No. 055387 MR2/ Cert. Unique ID 170774634**	**2023-12-12**	**DQS Med GmbH (CE0297)**	**DQS Med GmbH (CE0297)**	**2028**	**-**
Bands and Molar Bands with Prewelded Attachment						**-**
Brackets, Buccal Tubes and Accessories						**-**
Expansion Screws						**-**
Wires and Arches						**-**
Intra-Extra Oral						**-**
Coldpolimerizing Plastics						**-**
OrthoEasy Pin & Pal						**-**
Palatal Split Screw						**-**
Track Thermoforming Foils						**-**

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Preformed Wires & Springs						**-**