CE-CERTIFICADO

(Sistema completo de garantía de calidad)

Por la presente se certifica que la empresa

Bernhard Förster GmbH

Westliche Karl-Friedrich-Straße 151
75172 Pforzheim
Alemania

ha implantado y mantiene un sistema completo de garantía de calidad que se aplica a los productos en todas las fases, desde el diseño hasta los controles finales.

A través de una auditoría documentada en un informe, evaluada por DQS Medizinprodukte GmbH, se demostró que este sistema de garantía de calidad cumple las exigencias según

Anexo II – excluyendo el Punto 4 de la Directiva 93/42/CEE del Consejo relativa a los productos sanitarios

en relación con los siguientes productos sanitarios:

Productos ortodóncicos según lista del anexo

El fabricante estará sometido al control al que se hace referencia en el punto 5 del anexo II. El marcado CE con el número del organismo notificado (0297) se puede colocar a los productos enumerado en el certificado. Un certificado de examen CE del diseño según Anexo II, punto 4 hacen falta por los dispositivos de clase III que están contenido en este certificado. En el caso de dispositivos de clase Is el certificado està restringido a los aspectos de la fabricación que se refieran a la obtención y mantenimento de las condiciones de esterilidad. En el caso de dispositivos de clase Im el certificado está restringido a los aspectos de la fabricación relativos a la conformidad de los productos con los requisitos metrológicos.

Número de registro del certificado	055387 MR2
Número de indentificación único	170731106
Fecha de vigencia	2018-12-13
Fecha de vencimiento	2023-12-12
Frankfort del Meno, el	2018-12-13

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Directora

Dr. Thomas Feldmann
Director de la autoridad de certificación

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

DQS Medizinprodukte GmbH está un organismo notificado según la Directiva 93/42/CEE del Consejo relativa a los productos sanitarios con el número de identificación 0297.

Anexo al certificado
Número de registro del certificado: 055387 MR2
Número de indentificación único: 170731106
Fecha de vigencia: 2018-12-13

Bernhard Förster GmbH

Westliche Karl-Friedrich-Straße 151
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Familia del producto	Producto	Clase
Tornillos	Tornillos de expansión palatal	IIa
Alambres	Alambres y arcos de alambre y alambres preformados	IIa
Alambres con transmisión de carga	Alambres preformados y piezas de alambre con acción de resorte	IIa
Aditamentos	Brackets, tubos bucales y accesorios	IIa
Bandas	Bandas molares con y sin aditamentos soldados	IIa
Accesorios	Elástico para ligaduras, rotación y transmisión de fuerza para los dientes	IIa
Implantes	Tornillos ortodónticos para anclaje	IIb

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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.

Deutsche Bank AG
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						**-**