



EU Quality Management Certificate



This is to certify that the company

Bernhard Förster GmbH

Westliche Karl-Friedrich-Straße 151
75172 Pforzheim
Germany

SRN: DE-MF-000006256

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745 **Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation**

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	055387 MDR2017Q
Certificate ID	1000213926
Effective date	2025-02-06
Expiry date	2029-04-18
Frankfurt am Main,	2025-02-06



DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director



Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of the certification can only be verified by the QR-code.



Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000006256
Certificate ID: 1000213926

Device categories and variants covered by this certificate:

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Removable orthodontic screws
Risk classification: IIa
Basic-UDI-DI: ++EFOR010101CX
Intended purpose: Elements for removable or fixed orthodontic appliances for aligning teeth, correction of the occlusion or to obtain skeletal corrections during an orthodontic treatment by tooth borne or tooth tissue borne appliances

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Fixed orthodontic screws
Risk classification: IIa
Basic-UDI-DI: ++EFOR010102CZ
Intended purpose: Elements for removable or fixed orthodontic appliances for aligning teeth, correction of the occlusion or to obtain skeletal corrections during an orthodontic treatment by tooth borne or tooth tissue borne appliances

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Pre-formed wires and wires on spool
Risk classification: IIa
Basic-UDI-DI: ++EFOR020101DA
Intended purpose: Wires for fabrication of holding elements for removable orthodontic appliances

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Ligation wires
Risk classification: IIa
Basic-UDI-DI: ++EFOR020102DC
Intended purpose: Fixation of orthodontic wires in orthodontic attachments

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Arch wires (stainless steel alloy)
Risk classification: IIa
Basic-UDI-DI: ++EFOR020103DE
Intended purpose: Arch wires are components of fixed orthodontic appliances to align teeth during an orthodontic treatment

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Arch wires Betaflex (titanium-molybdenum alloy)
Risk classification: IIa
Basic-UDI-DI: ++EFOR020104DG
Intended purpose: Arch wires are components of fixed orthodontic appliances to align teeth during an orthodontic treatment



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Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Arch wires (chromium cobalt alloy)
Risk classification: IIa
Basic-UDI-DI: ++EFOR020105DJ
Intended purpose: Arch wires are components of fixed orthodontic appliances to align teeth during an orthodontic treatment

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Arch wires (nickel-titanium alloy)
Risk classification: IIa
Basic-UDI-DI: ++EFOR020106DL
Intended purpose: Archwires are components of fixed orthodontic appliances to align teeth during an orthodontic treatment

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Arch wires (Accessories)
Risk classification: IIa
Basic-UDI-DI: ++EFOR020107DN
Intended purpose: Orthodontic elements which are fixated on orthodontic wires to hold other components

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Springs
Risk classification: IIa
Basic-UDI-DI: ++EFOR030101DM
Intended purpose: Elements to be used in fixed appliances to apply spring forces for tooth movement during an orthodontic treatment

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Acrylics
Risk classification: IIa
Basic-UDI-DI: ++EFOR040101DY
Intended purpose: Acrylics to fabricate removable orthodontic appliances

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Thermoforming foils
Risk classification: IIa
Basic-UDI-DI: ++EFOR040202E7
Intended purpose: Plastic sheets/foils for patient-individual manufactured orthodontic appliances



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Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Ligature elastics
Risk classification: IIa
Basic-UDI-DI: ++EFOR060101EN
Intended purpose: Fixation of orthodontic wires in attachments bonded on teeth

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Elastics intra-oral
Risk classification: IIa
Basic-UDI-DI: ++EFOR060102EQ
Intended purpose: Elastic rubber bands to apply traction forces during orthodontic treatment

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Facebow (Facebow and Intra oral accessories)
Risk classification: IIa
Basic-UDI-DI: ++EFOR060203EX
Intended purpose: Intra-/extra-oral anchorage to induce skeletal corrections as part of dento-fascial orthopaedics

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Metal brackets conventional (milled)
Risk classification: IIa
Basic-UDI-DI: ++EFOR070101EZ
Intended purpose: Brackets are holding elements for fixed orthodontic appliances to correct the alignment of natural teeth and occlusion during orthodontic treatment

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Metal bracket conventional
Risk classification: IIa
Basic-UDI-DI: ++EFOR070102F3
Intended purpose: Brackets are holding elements for fixed orthodontic appliances to correct the alignment of natural teeth and occlusion during orthodontic treatment

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Metal bracket self-ligating
Risk classification: IIa
Basic-UDI-DI: ++EFOR070103F5
Intended purpose: Brackets are holding elements for fixed orthodontic appliances to correct the alignment of natural teeth and occlusion during orthodontic treatment



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Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Ceramic brackets conventional
Risk classification: IIa
Basic-UDI-DI: ++EFOR070104F7
Intended purpose: Brackets are holding elements for fixed orthodontic appliances to correct the alignment of natural teeth and occlusion during orthodontic treatment

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Ceramic brackets self-ligating
Risk classification: IIa
Basic-UDI-DI: ++EFOR070105F9
Intended purpose: Brackets are holding elements for fixed orthodontic appliances to correct the alignment of natural teeth and occlusion during orthodontic treatment

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Tubes
Risk classification: IIa
Basic-UDI-DI: ++EFOR070106FB
Intended purpose: Tubes are holding elements for fixed orthodontic appliances

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Lingual Brackets / Buttons
Risk classification: IIa
Basic-UDI-DI: ++EFOR070107FD
Intended purpose: Brackets/buttons are holding elements for fixed orthodontic appliances to correct the alignment of natural teeth and occlusion during orthodontic treatment

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Auxiliaries for attachments
Risk classification: IIa
Basic-UDI-DI: ++EFOR070109FH
Intended purpose: Auxiliary and holding elements for fixed orthodontic appliances

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Orthodontic bands
Risk classification: IIa
Basic-UDI-DI: ++EFOR080101FC
Intended purpose: Orthodontic bands with welded attachments transmit forces on 1st and 2nd molars or bicuspid



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Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Class II Appliances
Risk classification: IIa
Basic-UDI-DI: ++EFOR090101FP
Intended purpose: Appliance for treatment of class II malocclusions

Device category: **MDN 1209 - Non-active non-implantable dental materials**
Product name: Accessories for OrthoEasy
Risk classification: IIa
Basic-UDI-DI: ++EFOR100102D3
Intended purpose: Auxiliary devices for temporary fixed anchorage points for orthodontic appliances in the treatment of malpositioned teeth and jaws and the masticatory system

Examinations and tests performed:

055387 A213542MED MDR2017Q dated 2024-02-02
055387_A212621MED_Ceramic brackets self ligating dated 2023-12-16
055387_A212621MED_Fixed orthodontic screws dated 2023-12-16

Further conditions for or limitations to the validity of the certificate:

n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2024-04-19	1000145868	Remove the product "OrthoEasy anchorage screw"