EU Quality Management Certificate

This is to certify that the company

DÜRR DENTAL SE

Höpfigheimer Str. 17
74321 Bietigheim-Bissingen
Germany

SRN: DE-MF-000006032

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.	518373 MDR2017Q
Certificate ID	1000167583
Effective date	2024-03-14
Expiry date	2027-03-10
Frankfurt am Main,	2024-03-14

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

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 this certificate can only be verified by the QR-code.

420.90 Version 6.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000006032
Certificate ID: 1000167583

Device categories and variants covered by this certificate:

Device category:	**MDA 0204 - Other active non-implantable devices for monitoring and/or diagnosis**
Product name:	VistaRay Sensor 7.1, VistaRay Sensor 7.2
Risk classification:	IIa
Basic-UDI-DI:	++E2471033Y3
Intended purpose:	The intraoral sensor converts x-rays into digital image information and provides it to a dental software.

Device category:	**MDA 0204 - Other active non-implantable devices for monitoring and/or diagnosis**
Product name:	SensorX Size #1, SensorX Size #2
Risk classification:	IIa
Basic-UDI-DI:	++E2471034Y5
Intended purpose:	The intraoral sensor converts x-rays into digital image information and provides it to a dental software.

Device category:	**MDA 0311 - Active non-implantable dental devices**
Product name:	Tornado 1, Tornado 2, Tornado 2+, Tornado 4
Risk classification:	IIa
Basic-UDI-DI:	++E2471007Y2
Intended purpose:	The compressor is designed to supply compressed air for dental applications.

Device category:	**MDA 0311 - Active non-implantable dental devices**
Product name:	Primo, Duo, Duo Tandem, Trio, Quattro, Quattro Tandem, Quattro P 20
Risk classification:	IIa
Basic-UDI-DI:	++E2471008Y4
Intended purpose:	The compressor is designed to supply compressed air for dental applications.

Device category:	**MDA 0311 - Active non-implantable dental devices**
Product name:	P 6000 Compressor Module, Tank Module 50 Hz, Tank Module 60 Hz, Tank Module CN, P 9000 Compressor Module, P 12000 Compressor Module
Risk classification:	IIa
Basic-UDI-DI:	++E2471009Y6
Intended purpose:	The compressor is designed to supply compressed air for dental applications.

Device category:	**MDA 0311 - Active non-implantable dental devices**
Product name:	Tyscor V 20, Tyscor V 30, V 12000, V 15000, V 6000, V 9000, V 18000
Risk classification:	IIa
Basic-UDI-DI:	++E2471042Y4
Intended purpose:	The suction unit provides the dental treatment unit with vacuum and volume flow.

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Device category:	**MDA 0311 - Active non-implantable dental devices**
Product name:	Tyscor V 1 Plus, Tyscor V 2, Tyscor V 4, Tyscor V 2 Plus, V 1200 S, V 2400, V 300 S, V 600, V 900 S
Risk classification:	IIa
Basic-UDI-DI:	++E2471040XY
Intended purpose:	The suction unit provides the dental treatment unit with vacuum and volume flow.

Device category:	**MDA 0311 - Active non-implantable dental devices**
Product name:	Tyscor VS 2, Tyscor VS 1 Plus, Tyscor VS 4, Tyscor VS 2 Plus, VS 1200 S, VS 250 S, VS 300 S, VS 600, VS 900 S
Risk classification:	IIa
Basic-UDI-DI:	++E2471041Y2
Intended purpose:	The suction unit provides the dental treatment unit with vacuum and volume flow.

Device category:	**MDA 0311 - Active non-implantable dental devices**
Product name:	Variosuc VS, Variosuc VSA
Risk classification:	IIa
Basic-UDI-DI:	++E2471043Y6
Intended purpose:	The moveable spray mist suction unit generates a vacuum and a volume flow for dental treatment.

Device category:	**MDA 0311 - Active non-implantable dental devices**
Product name:	VC 65
Risk classification:	IIa
Basic-UDI-DI:	++E2471045YA
Intended purpose:	The suction unit provides the user in dental surgery, orthodontic practice, dental clinic and/or oral and maxillofacial surgery with vacuum and volume flow

Device category:	**MDA 0311 - Active non-implantable dental devices**
Product name:	VSA 300 S
Risk classification:	IIa
Basic-UDI-DI:	++E2471044Y8
Intended purpose:	The suction machine provides a suction output to the dental treatment unit and is designed for continuous separation of liquids and air and for separation of amalgam from the entire waste water from dental treatment units.

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Device category:	**MDA 0311 - Active non-implantable dental devices**
Product name:	MyLUNOS Body KaVo, MyLUNOS Body Sirona, MyLUNOS Body W&H, MyLUNOS Body Bien Air, MyLUNOS Body NSK, LUNOS Perio Tips, MyLUNOS container blue, MyLUNOS container orange, MyLUNOS container mint, MyLUNOS container cherry red, MyLUNOS Supra nozzle, MyLUNOS container violet, MyLUNOS Perio nozzle
Risk classification:	IIa
Basic-UDI-DI:	++E2471010XP
Intended purpose:	This device is a powder jet handpiece for use in dental applica-tions. It is used predominantly for the removal of plaques, de-posits and discolorations on teeth, as well as for the cleaning of brackets, dental braces, crowns and bridges. In addition, the device can also be used to assist with the treatment of perio-dontal defects.

Device category:	**MDA 0311 - Active non-implantable dental devices**
Product name:	Scaler Handpiece, Vector Handpiece, Tool Kit Scaler P1, Tool Kit Scaler P2, Tool Kit Scaler P3, Tool Kit Scaler P4, Paro curette, Paro lancet, Paro probe plus, Paro probe straight, Paro probe curved, Supra probe flexible, Recall Probe straight, Recall Curette, Periimplant hard, Periimplant soft, Vector Easy, Vector, Vector Scaler
Risk classification:	IIa
Basic-UDI-DI:	++E2471011XR
Intended purpose:	This device is a piezo-operated ultrasonic device for use in dental applications. It is mainly used for the treatment of periodontal defects. In addition, the device is used in the area of prophylaxis, periimplantitis treatment as well as dental hygiene.

Device category:	**MDA 0315 - Standalone software**
Product name:	DBSWIN 5.17
Risk classification:	IIb
Basic-UDI-DI:	++E2471039YF
Intended purpose:	DBSWIN and VistaEasy imaging software is an image management system that allows dentists to acquire, display, edit, view, store, print, and distribute medical images. DBSWIN and VistaEasy software runs on user provided PC-compatible computers and utilize previously cleared digital image capture devices for image acquisition. VistaEasy is included as part of DBSWIN. It provides additional interfaces for Third Party Software. VistaEasy can also be used by itself, as a defeatured version of DBSWIN.

Device category:	**MDA 0315 - Standalone software**
Product name:	VistaSoft 3.0, VisionX 3.0
Risk classification:	IIb
Basic-UDI-DI:	++E2471038YD
Intended purpose:	The software features functions for recording, displaying, analysing, diagnosing, managing and sending digital or digitised 2D and 3D images and videos in dental practices and specialist dental clinics.

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Device category:	**MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name:	Universal Cannula, d=16 mm grey, pink, blue, turquoise, yellow Universal Cannula Petito, d=16mm grey, yellow, blue, pink, turquoise, Universal Cannula Petito, d=11mm, grey, yellow, blue Universal Cannula Protect, d=16 mm grey, yellow, blue
Risk classification:	IIa
Basic-UDI-DI:	++E2471046YC
Intended purpose:	As part of a dental suction system, the cannula is designed to collect media from the mouth of the patient with the aid of the suction provided via a vacuum.

Device category:	**MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name:	Prophylaxis Cannula, d=16 mm grey
Risk classification:	IIa
Basic-UDI-DI:	++E2471047YE
Intended purpose:	As part of a dental suction system, the cannula is designed to collect media from the mouth of the patient with the aid of the suction provided via a vacuum.

Device category:	**MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Product name:	Surgical Cannula for single use
Risk classification:	IIa
Basic-UDI-DI:	++E2471048YG
Intended purpose:	As part of a dental suction system, the sterile cannula for single use is designed to collect media from the mouth of the patient with the aid of the suction provided via a vacuum.

Device category:	**MDA 0201 - Active non-implantable imaging devices utilising ionizing radiation**
Product name:	VistaVox S, VistaVox S Ceph, ProVecta 3D Prime, ProVecta 3D Prime Ceph
Risk classification:	IIb
Basic-UDI-DI:	++E2471035Y7
Intended purpose:	Creation of 3D, panoramic and optionally cephalometric X-ray images in dental radiography for adult and adolescent patients.

Device category:	**MDA 0317/A - Active non-implantable devices for cleaning and disinfection**
Product name:	Hygosuc basis, Hygosuc CDS 1, Hygosuc CDS 60
Risk classification:	IIa
Basic-UDI-DI:	++E2471013XV
Intended purpose:	Dosing and supply of a ready-to-use disinfection solution for the subsequent cleaning, disinfection and care of a dental suction system.

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Device category:	**MDA 0317/A - Active non-implantable devices for cleaning and disinfection**
Product name:	Hygojet
Risk classification:	IIa
Basic-UDI-DI:	++E2471012XT
Intended purpose:	Dürr Dental Hygojet is a hygiene lock and applies water, compressed air and disinfectant for cleaning and disinfection sheath for impressions and prosthetic work.

Device category:	**MDN 1207 - Non-active non-implantable diagnostic devices**
Product name:	VistaScan Image Plate Plus S4, VistaScan Image Plate Plus S3, VistaScan Image Plate Plus S2, VistaScan Image Plate Plus S1, VistaScan Image Plate Plus S0, VistaScan Image Plate Plus ID S2, VistaScan Image Plate Plus ID S0, VistaScan Image Plate IQ S4, VistaScan Image Plate IQ S3, VistaScan Image Plate IQ S2, VistaScan Image Plate IQ S1, VistaScan Image Plate IQ S0, Planmeca Imaging Plate Size 2, Planmeca Imaging Plate Size 1, Planmeca Imaging Plate Size 0, Imaging Plate Size 0, Imaging Plate Size 1, Imaging Plate Size 2
Risk classification:	IIa
Basic-UDI-DI:	++E2471015XZ
Intended purpose:	The reusable image plates are used to store intraoral or extraoral x-ray images in dental applications.

Device category:	**MDN 1207 - Non-active non-implantable diagnostic devices**
Product name:	Phosphor Storage Plate IDX S4, Phosphor Storage Plate IDX S3, Phosphor Storage Plate IDX S2, Phosphor Storage Plate IDX S1, Phosphor Storage Plate IDX S0, Phosphor Storage Plate S0, Phosphor Storage Plate S1, Phosphor Storage Plate S2, Phosphor Storage Plate S3, Phosphor Storage Plate S4
Risk classification:	IIa
Basic-UDI-DI:	++E2471017Y5
Intended purpose:	The reusable image plates are used to store intraoral or extraoral x-ray images in dental applications.

Device category:	**MDN 1207 - Non-active non-implantable diagnostic devices**
Product name:	VistaScan Image Plate 240x300, VistaScan Image Plate 200x240, VistaScan Image Plate 180x240, VistaScan Image Plate 150x300, VistaScan Image Plate 127x305
Risk classification:	IIa
Basic-UDI-DI:	++E2471016Y3
Intended purpose:	The reusable image plates are used to store intraoral or extraoral x-ray images in dental applications.

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Device category:	**MDA 0311 - Active non-implantable dental devices**
Product name:	Power Tower Silence 120
Risk classification:	IIa
Basic-UDI-DI:	++E2471056YF
Intended purpose:	Noise-insulated central supply of dental compressed air as well as negative pressure for dental suction. Optionally, water and amalgam can be separated.

Device category:	**MDA 0311 - Active non-implantable dental devices**
Product name:	Power Tower View
Risk classification:	IIa
Basic-UDI-DI:	++E2471057YH
Intended purpose:	Noise-insulated central supply of dental compressed air as well as negative pressure for dental suction. Optionally, water and amalgam can be separated.

Examinations and tests performed:
518373 A207658MED Audit report MDR Stage II dated 2021-08-16
420_12e_Report_TechnicalFileReviewCanulasDuerrV32021-05-17 dated 2021-08-09
418373_Bericht_Produktprüfung_vistaray_2 dated 2022-03-03
518373_A207658MED_01 TD MDR Tornado 1, Tornado 2, Tornado 2+, Tornado 4 dated 2021-07-30
518373_A208895MED_420_12d_Bericht_Produktprüfung-20220104 dated 2022-01-08
518373_A207658MED_420_12d_Bericht_Produktprüfung-Aufbissstab-20220209 dated 2022-02-16
518373_A207658MED_VistaVox dated 2022-06-17
518373_A207658MED_05 Hygosuc dated 2023-02-17
518373_A212021MED_06 Image Plates dated 2023-11-03
518373_A210787MED_07 Power Tower Silence 120 dated 2024-02-11

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	2022-03-11	170778794	Addition of the product VistaVox S
02	2022-06-27	170780266	Removal of the product Bite Block and Addition Hygosuc
03	2023-02-23	170782386	Addition of the product “image plates”
04	2023-12-14	1000147105	Addition of the product Power Tower Silence 120