



# CERTIFICATE



This is to certify that the company

## DÜRR DENTAL SE

Höpfigheimer Str. 17  
74321 Bietigheim-Bissingen  
Germany

has implemented a complete Quality Management System for each phase from Design to Final Testing of the products.

Through an audit, documented in a report, carried out by DQS Medizinprodukte GmbH, the proof was provided that this quality management system meets the requirements according to

### Annex IX of Regulation (EU) 2017/745

**CONFORMITY ASSESSMENT PROCEDURE ON THE BASIS OF A QUALITY MANAGEMENT SYSTEM AND AN ASSESSMENT OF THE TECHNICAL DOCUMENTATION**

regarding the medical devices listed in the Annex:

The manufacturer shall be subject to surveillance in accordance with Annex IX, Chapter 1, Section 3. The CE marking with the identification number of the Notified Body (0297) may be affixed on the devices listed on the certificate.

In case of devices placed on the market in sterile condition, devices with a measuring function or for devices which are reusable surgical instruments, the involvement of the Notified Body in these procedures shall be limited: in case of products that are placed on the market in sterile condition, limited to the aspects of manufacture concerned with securing and maintaining sterile condition; in the case of devices with a measuring function limited to the aspects related to the conformity of the devices with the metrological requirements; in the case of reusable surgical instruments limited to the aspects related to reuse, in particular cleaning, disinfection, sterilisation, maintenance and functional testing, as well as the related instructions for use.

Certificate registration no.	DE-MF-000006032
Certificate ID	170778795
Previous certificate-ID	n/a
Effective date	2022-03-11
Expiry date	2027-03-10
Frankfurt am Main,	2022-03-11



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

## DQS Medizinprodukte GmbH

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**DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.**



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Product name	Model	Type	Intended Use	Risk-class	Basic UDI-DI
EQUIPMENT FOR DIGITAL ENDORAL RADIOLOGY	-VistaRay Sensor 7.1 -VistaRay Sensor 7.2	n/a	The intraoral sensor converts x-rays into digital image information and provides it to a dental software.	Ila	++E2471033Y3
EQUIPMENT FOR DIGITAL ENDORAL RADIOLOGY	-SensorX Size #1 -SensorX Size #2	n/a	The intraoral sensor converts x-rays into digital image information and provides it to a dental software.	Ila	++E2471034Y5
MEDICAL CHAIRS - ACCESSORIES	-Tornado 1 -Tornado 2 -Tornado 2+ -Tornado 4	n/a	The compressor is designed to supply compressed air for dental applications.	Ila	++E2471007Y2
MEDICAL CHAIRS - ACCESSORIES	-Primo -Duo -Duo Tandem -Trio -Quattro -Quattro Tandem -Quattro P 20	n/a	The compressor is designed to supply compressed air for dental applications.	Ila	++E2471008Y4
MEDICAL CHAIRS - ACCESSORIES	-P 6000 Compressor Module -Tank Module 50 Hz -Tank Module 60 Hz -Tank Module CN -P 9000 Compressor Module -P 12000 Compressor Module	n/a	The compressor is designed to supply compressed air for dental applications.	Ila	++E2471009Y6
MEDICAL CHAIRS - ACCESSORIES	-Tyscor V 20 -Tyscor V 30 - V 12000 - V 15000 - V 6000 - V 9000 - V 18000	n/a	The suction unit provides the dental treatment unit with vacuum and volume flow.	Ila	++E2471042Y4



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MEDICAL CHAIRS - ACCESSORIES	-Tyscor V 1 -Tyscor V 2 -Tyscor V 4 -V 1200 S -V 2400 -V 300 S -V 600 -V 900 S	n/a	The suction unit provides the dental treatment unit with vacuum and volume flow.	Ila	++E2471040XY
MEDICAL CHAIRS - ACCESSORIES	-Tyscor VS 2 -Tyscor VS 1 -Tyscor VS 4 -VS 1200 S -VS 250 S -VS 300 S -VS 600 -VS 900 S	n/a	The suction unit provides the dental treatment unit with vacuum and volume flow.	Ila	++E2471041Y2
MEDICAL CHAIRS - ACCESSORIES	-Variosuc VS -Variosuc VSA	n/a	The moveable spray mist suction unit generates a vacuum and a volume flow for dental treatment.	Ila	++E2471043Y6
MEDICAL CHAIRS - ACCESSORIES	-VC 65	n/a	The suction unit provides the user in dental surgery, orthodontic practice, dental clinic and/or oral and maxillofacial surgery with vacuum and volume flow.	Ila	++E2471045YA
MEDICAL CHAIRS - ACCESSORIES	-VSA 300 S	n/a	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.	Ila	++E2471044Y8



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DENTAL PROPHYLAXIS EQUIPMENT	-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	n/a	This device is a powder jet handpiece for use in dental applications. 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.	Ila	++E2471010XP
DENTAL PROPHYLAXIS EQUIPMENT	-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 -Recall Probe straight	n/a	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.	Ila	++E2471011XR



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	-Supra probe flexible -Recall Curette -Periimplant hard -Periimplant soft -Vector Easy -Paro curette -Vector -Vector Scaler				
SYSTEMS FOR DIRECT DIGITAL RADIOLOGY (DR) - MEDICAL DEVICE SOFTWARE	-DBSWIN 5.17	n/a	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	IIb	++E2471039YF
SYSTEMS FOR DIRECT DIGITAL RADIOLOGY (DR) - MEDICAL DEVICE SOFTWARE	-VistaSoft 3.0 -VisionX 3.0	n/a	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.	IIb	++E2471038YD



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SALIVA ASPIRATORS AND SALIVA ABSORBENTS	-Universal Cannula, d=16 mm, grey -Universal Cannula, d=16 mm, yellow - Universal Cannula, d=16 mm, pink - Universal Cannula, d=16 mm, blue -Universal Cannula, d=16 mm, turquoise -Universal Cannula Petito, d=16mm, grey -Universal Cannula Petito, d=11mm, yellow -Universal Cannula Petito, d=11mm, blue - Universal Cannula Petito, d=16mm, pink -Universal Cannula Petito, d=16mm, turquoise -Universal Cannula Petito, d=11mm, grey -Universal Cannula Petito, d=11mm, yellow -Universal Cannula Protect, d=16 mm, grey -Universal Cannula Protect, d=16 mm, yellow -Universal Cannula Protect, d=16 mm, blue	N/a	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.	Ila	++E2471046YC
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SALIVA ASPIRATORS AND SALIVA ABSORBENTS	-Prophylaxis cannula, d=16 mm, grey	n/a	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.	Ila	++E2471047YE
SALIVA ASPIRATORS AND SALIVA ABSORBENTS	-Surgical Cannula for single use, d=2.5 mm	n/a	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.	Ila	++E2471048YG
SYSTEMS FOR DIRECT DIGITAL RADIOLOGY (DR) - HARDWARE ACCESSORIES	-Bite block	N/a	The accessory is intended to enable positioning of the patient's jaw. The accessory is intended to be used in the oral cavity of the patient und can be sterilized before use by the user. The accessories are used to fulfill the Intended purpose of the VistaVox family.	Ila	++E2471037YB

Examinations and tests performed (e.g. Reference to relevant CS, harmonised standards, test reports and audit report):

ReportMDRStufe2Duerr-Dentalrev2 dated 2021-12-31

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

Reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device or devices covered:

n/a

Conditions or limitations regarding the validity of the certificate:

n/a

This annex is only valid in connection with the above-mentioned certificate.