EU - KONFORMITÄTSERKLÄRUNG
EC - DECLARATION OF CONFORMITY

Name des Herstellers / Manufacturer	**DÜRR DENTAL SE**
Anschrift des Herstellers / Address	**Höpfigheimer Str. 17** **74321 Bietigheim-Bissingen** **Germany**
Single Registration Number	**DE-MF-000006032**
Technische Dokumentation / Technical File	**CE-110-A, CE-110-B, CE-110-C**
Produktfamilie / Product Family	**Suction System VS & Tyscor VS**

Zweckbestimmung:
Die Saugmaschine/Saugeinheit stellt der dentalen Behandlungseinheit in der Zahnarztpraxis und/oder Zahnklinik einen Unterdruck und einen Volumenstrom zur Verfügung.

Intended purpose:
The suction unit provides the dental treatment unit with vacuum and volume flow.

Wir erklären hiermit, dass die auf den folgenden Seiten beschriebenen Artikel den einschlägigen Bestimmungen der Verordnung 2017/745 über Medizinprodukte in der gültigen Fassung entsprechen.
We hereby declare that the devices described on the following pages conform to the relevant provisions of the Medical Device Regulation 2017/745, as amended.

Konformitätsbewertungsverfahren gemäß Anhang IX Kapitel I, II (Abschnitt 4) und III MDR. Das Konformitätsbewertungsverfahren wurde, mit Beteiligung der Benannten Stelle DQS Medizinprodukte GmbH, August-Schanz-Str. 21, D-60433 Frankfurt a.M. (Kennnummer 0297) durchgeführt. Zertifikatsnummer: 170778795
Conformity assessment procedure according to Annex IX Chapter I, II (section 4) und III MDR. The conformity assessment procedure was carried out with the participation of the Notified Body DQS Medizinprodukte GmbH, August-Schanz-Str. 21, D-60433 Frankfurt a. M. (identification number 0297). Number of certificate: 170778795

Wir erklären die Erfüllung der Richtlinie zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten 2011/65/EU in der gültigen Fassung.
We hereby declare conformity to the relevant provisions of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment, as amended.

Dürr Dental trägt die alleinige Verantwortung für die Ausstellung der Konformitätserklärung.
Dürr Dental is solely responsible for the issuance of the declaration of conformity.

Diese Erklärung gilt für Produkte, die bis zum 2027-03-10 in Verkehr gebracht werden.
This declaration applies to devices that are placed on the market on or before 2027-03-10.

Bietigheim-Bissingen, den / date 2022-05-19

i. V. J. Gramann
Leitung Forschung und Entwicklung
Director of Research & Development

i. V. O. Lange
Leitung Qualitätsmanagement
Director of Quality Management

Basis-UDI-DI: Basic UDI-DI:	Referenznummer: Reference number:	Produktbezeichnung: Product name:	Referenznummer ist enthalten in folgenden Verkaufsartikelnummern: Reference number is enclosed in following sales part numbers:	Klassifizierung: Classification:	CE-Kennzeichnung ab Chargen- / Seriennummer: CE- mark starting with batch- / serial number:
++E2471041Y2	7151300100	VS 250 S	N/A	IIa	P468856001
++E2471041Y2	7151300200	VS 250 S	N/A	IIa	P468856001
++E2471041Y2	7151-01	VS 250 S	N/A	IIa	P468856001
++E2471041Y2	7151-01/002	VS 250 S	N/A	IIa	P468856001
++E2471041Y2	7151-02	VS 250 S	N/A	IIa	P468856001
++E2471041Y2	7151-02/002	VS 250 S	N/A	IIa	P468856001
++E2471041Y2	7122-01	VS 300 S	N/A	IIa	P468856001
++E2471041Y2	7122-01/002	VS 300 S	N/A	IIa	P468856001
++E2471041Y2	7122-01/021	VS 300 S	N/A	IIa	P468856001
++E2471041Y2	7122-02	VS 300 S	N/A	IIa	P468856001
++E2471041Y2	7122-02/002	VS 300 S	N/A	IIa	P468856001
++E2471041Y2	7122-03	VS 300 S	N/A	IIa	P468856001
++E2471041Y2	7122-03/002	VS 300 S	N/A	IIa	P468856001
++E2471041Y2	7122-04	VS 300 S	N/A	IIa	P468856001
++E2471041Y2	7122-04/002	VS 300 S	N/A	IIa	P468856001
++E2471041Y2	7122-05/003	VS 300 S	N/A	IIa	P468856001
++E2471041Y2	7128-01	VS 600	7128-01/002	IIa	P468856001
++E2471041Y2	7128-01/021	VS 600	N/A	IIa	P468856001
++E2471041Y2	7128-02	VS 600	7128-02/002,	IIa	P468856001
			7128-02/003	IIa	P468856001
++E2471041Y2	7128100900	VS 600	N/A	IIa	P468856001
++E2471041Y2	7134-01	VS 900 S	7134-01/002	IIa	P468856001
++E2471041Y2	7134-01/021	VS 900 S	N/A	IIa	P468856001
++E2471041Y2	7134-02	VS 900 S	7134-02/002,	IIa	P468856001
			7134-02/003	IIa	P468856001
++E2471041Y2	7134-02/021	VS 900 S	N/A	IIa	P468856001
++E2471041Y2	7138-02	VS 1200 S	7138-02/002,	IIa	P468856001
			7138-02/003	IIa	P468856001
++E2471041Y2	7138-02/021	VS 1200 S	N/A	IIa	P468856001
++E2471041Y2	7138-03	VS 1200 S	7138-03/002,	IIa	P468856001
			7138-03/003	IIa	P468856001

Basis-UDI-DI: Basic UDI-DI:	Referenznummer: Reference number:	Produktbezeichnung: Product name:	Referenznummer ist enthalten in folgenden Verkaufsartikelnummern: Reference number is enclosed in following sales part numbers:	Klassifizierung: Classification:	CE-Kennzeichnung ab Chargen- / Seriennummer: CE- mark starting with batch- / serial number:
++E2471041Y2	7138100900	VS 1200 S	N/A	IIa	P468856001
++E2471041Y2	7182100100	Tyscor VS 1	N/A	IIa	P468856001
++E2471041Y2	7186-01	Tyscor VS 2	N/A	IIa	P468856001
++E2471041Y2	7188200100	Tyscor VS 4	N/A	IIa	P468856001
++E2471041Y2	7188100100	Tyscor VS 4	N/A	IIa	P468856001
++E2471041Y2	7188100900	Tyscor VS 4	N/A	IIa	P468856001

EU - KONFORMITÄTSERKLÄRUNG
EC - DECLARATION OF CONFORMITY

Name des Herstellers / Manufacturer	**DÜRR DENTAL SE**
Anschrift des Herstellers / Address	**Höpfigheimer Str. 17** **74321 Bietigheim-Bissingen** **Germany**
Single Registration Number	**DE-MF-000006032**
Technische Dokumentation / Technical File	**CE-100-B**
Produktfamilie / Product Family	**Tornado Compressor**

Zweckbestimmung:
Der Kompressor ist für die Bereitstellung von komprimierter Luft für dentalmedizinische Anwendungen bestimmt.

Intended purpose:
The compressor is designed to supply compressed air for dental applications.

Wir erklären hiermit, dass die auf den folgenden Seiten beschriebenen Artikel den einschlägigen Bestimmungen der Verordnung 2017/745 über Medizinprodukte in der gültigen Fassung entsprechen.
We hereby declare that the devices described on the following pages conform to the relevant provisions of the Medical Device Regulation 2017/745, as amended.

Konformitätsbewertungsverfahren gemäß Anhang IX Kapitel I, II (Abschnitt 4) und III MDR. Das Konformitätsbewertungsverfahren wurde, mit Beteiligung der Benannten Stelle DQS Medizinprodukte GmbH, August-Schanz-Str. 21, D-60433 Frankfurt a.M. (Kennnummer 0297) durchgeführt. Zertifikatsnummer: 170778795
Conformity assessment procedure according to Annex IX Chapter I, II (section 4) und III MDR. The conformity assessment procedure was carried out with the participation of the Notified Body DQS Medizinprodukte GmbH, August-Schanz-Str. 21, D-60433 Frankfurt a. M. (identification number 0297). Number of certificate: 170778795

Wir erklären die Erfüllung der Richtlinie zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten 2011/65/EU in der gültigen Fassung.
We hereby declare conformity to the relevant provisions of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment, as amended.

Dürr Dental trägt die alleinige Verantwortung für die Ausstellung der Konformitätserklärung.
Dürr Dental is solely responsible for the issuance of the declaration of conformity.

Diese Erklärung gilt für Produkte, die bis zum 2027-03-10 in Verkehr gebracht werden.
This declaration applies to devices that are placed on the market on or before 2027-03-10.

Bietigheim-Bissingen, den / date 2022-05-19

i. V. J. Gramann
Leitung Forschung und Entwicklung
Director of Research & Development

i. V. O. Lange
Leitung Qualitätsmanagement
Director of Quality Management

Basis-UDI-DI: Basic UDI-DI:	Referenznummer: Reference number:	Produktbezeichnung: Product name:	Referenznummer ist enthalten in folgenden Verkaufsartikelnummern: Reference number is enclosed in following sales part numbers:	Klassifizierung: Classification:	CE-Kennzeichnung ab Chargen- / Seriennummer: CE- mark starting with batch- / serial number:
++E2471007Y2	5180-01	Tornado 1	N/A	IIa	P468856001
++E2471007Y2	5180-02	Tornado 1	N/A	IIa	P468856001
++E2471007Y2	5180-03	Tornado 1	N/A	IIa	P468856001
++E2471007Y2	5182-01	Tornado 1	N/A	IIa	P468856001
++E2471007Y2	5182-02	Tornado 1	N/A	IIa	P468856001
++E2471007Y2	5182-03	Tornado 1	N/A	IIa	P468856001
++E2471007Y2	5185-01	Tornado 1	N/A	IIa	P468856001
++E2471007Y2	5186-01	Tornado 1	N/A	IIa	P468856001
++E2471007Y2	5280-01	Tornado 2	N/A	IIa	P468856001
++E2471007Y2	5280-03	Tornado 2	N/A	IIa	P468856001
++E2471007Y2	5282-01	Tornado 2	N/A	IIa	P468856001
++E2471007Y2	5282-03	Tornado 2	N/A	IIa	P468856001
++E2471007Y2	5285-01	Tornado 2	N/A	IIa	P468856001
++E2471007Y2	5286-01	Tornado 2	N/A	IIa	P468856001
++E2471007Y2	5282100029	Tornado 2	N/A	IIa	P468856001
++E2471007Y2	5286100036	Tornado 2+	N/A	IIa	P468856001
++E2471007Y2	4280-01	Tornado 4	N/A	IIa	P468856001
++E2471007Y2	4282-01	Tornado 4	N/A	IIa	P468856001
++E2471007Y2	4282-03	Tornado 4	N/A	IIa	P468856001
++E2471007Y2	4280100022	Tornado 4	N/A	IIa	P468856001
++E2471007Y2	4282100006	Tornado 4	N/A	IIa	P468856001

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 devised 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.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

Annex to the EU certificate on the Assessment of the Technical Documentation
Certificate registration No.: DE-MF-000006032
Certificate ID: 170778795
Effective date: 2022-03-11

DÜRR DENTAL SE

Höpfigheimer Str. 17
74321 Bietigheim-Bissingen
Germany

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.	IIa	++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.	IIa	++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.	IIa	++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.	IIa	++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.	IIa	++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.	IIa	++E2471042Y4

Annex to the EU certificate on the Assessment of the Technical Documentation
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Certificate ID: 170778795
Effective date: 2022-03-11

DÜRR DENTAL SE

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74321 Bietigheim-Bissingen
Germany

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.	IIa	++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.	IIa	++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.	IIa	++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.	IIa	++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.	IIa	++E2471044Y8

Annex to the EU certificate on the
Assessment of the Technical Documentation
Certificate registration No.: DE-MF-000006032
Certificate ID: 170778795
Effective date: 2022-03-11

DÜRR DENTAL SE

Höpfigheimer Str. 17
74321 Bietigheim-Bissingen
Germany

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 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.	IIa	++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.	IIa	++E2471011XR

Annex to the EU certificate on the Assessment of the Technical Documentation
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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

Annex to the EU certificate on the Assessment of the Technical Documentation
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Effective date: 2022-03-11

DÜRR DENTAL SE

Höpfigheimer Str. 17
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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.	IIa	++E2471046YC

Annex to the EU certificate on the Assessment of the Technical Documentation
Certificate registration No.: DE-MF-000006032
Certificate ID: 170778795
Effective date: 2022-03-11

DÜRR DENTAL SE

Höpfigheimer Str. 17
74321 Bietigheim-Bissingen
Germany

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.	IIa	++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.	IIa	++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.	IIa	++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.

DÜRR DENTAL SE · Postfach 1264 · 74302 Bietigheim-Bissingen

To the trade

DÜRR DENTAL SE
Höpfigheimer Str. 17
74321 Bietigheim-Bissingen
Deutschland / Germany
Tel +49 7142 705-0
Fax +49 7142 705-500
E-Mail info@duerrdental.com
Internet www.duerrdental.com

Unsere Zeichen / Our Ref. Tel Fax E-Mail

Datum / Date
20th September 2022

Air quality of Duerr Dental compressor stations

Dear Sir or Madame,

we hereby confirm that the compressed air provided by Duerr Dental Silver Airline and Tornado compressors with dry air systems fulfills the following air quality classes, which correspond to the purity classes [2:4:2] according to ISO 22052:2020 or ISO 8573-1:2010:

Particle class 2	The numbers of particle in the dental ai rare as follows: Particle size — Number of particles per cubic meter 0,1 µm < d ≤ 0,5 µm — ≤ 400 000 0,5 µm < d ≤ 1,0 µm — ≤ 6 000 1,0 µm < d ≤ 5,0 µm — ≤ 100
Humidity class 4	The pressure dewpoint is ≤ +3 °C at 20°C medium temperature and at 0,7 MPa constant system pressure
Oil content class2	The oil content of dental air is ≤ 0,1 mg / m^3

Dürr Dental compressors are classified as type 2 (non-oil-lubricated compressors) according to ISO 22052-2020.

Air quality testing of our compressors was performed on representative Silver Airline and Tornado series compressors in accordance with the appropriate specifications of the standard and with an ULPA U16 bacteria filter installed.

Kind regards,

i. A. Dr. Jens Gramann
Director BU Equipment R&D

SOUTH AFRICAN HEALTH PRODUCT REGULATORY AUTHORITY

SAHPRA South African Health Products Regulatory Authority
Building A
Loftus Park
402 Kirkness Street
Arcadia
0083
Web: www.sahpra.org.za/radiation-control

DUERR DENTAL SOUTH AFRICA
137 Libertas Street
NOORDHEUWEL
1739

Enquiries:
X-Ray Devices: Import.xrays@sahpra.org.za
All Other Devices:
nirmed.enquiry@sahpra.org.za

Reference: 1827/33744
Date: 19 December 2023

Attention: Luigi Ragni

- **This updated document contains the licences for electromedical devices as well as the licence conditions that are currently valid, and replaces the document dated 3 October 2022 and all previous documents.**
- Apart from the other licensing considerations, the licence for each individual model is issued on the strength of the fact that the intended purpose, as stated in the application form, is considered to be in agreement with the intended purpose of the device as reflected in the manufacturer's labelling and instructions for use (i.e. documentation required in terms of the certification process according to EC Directive 93/42/EEC or 90/385/EEC, whichever is applicable).
- The licence for each model remains valid only while the EC compliance documentation is valid.
- The safety and performance of all the licensed models remain the responsibility of the licence holder.
- Inspections may be performed to ascertain whether the licence conditions are being adhered to.

Yours faithfully

Boitumelo Semete-Makokotlela

Chief Executive Officer

SAHPRA

RADIATION CONTROL

LICENCE HOLDER: DUERR DENTAL SOUTH AFRICA

ADDRESS: 137 Libertas Street , NOORDHEUWEL , Mogale

LIST OF LICENCES TO IMPORT NEW ELECTROMEDICAL DEVICES HAZARDOUS SUBSTANCES ACT (ACT 15 OF 1973)

LICENCE NUMBER	BRAND	MODEL	LICENCE CONDITIONS
1827/33745	DURR DENTAL	VISTARAY	01, 03, 09
1827/33746	DURR DENTAL	VISTAVOX S	01, 03, 09
1827/33747	DURR DENTAL	VISTAVOX S CEPH	01, 03, 09
1827/33754	DURR DENTAL	VISTASCAN COMBI VIEW	01, 03, 09
1827/33755	DURR DENTAL	VISTASCAN MINI VIEW	01, 03, 09
1827/33756	DURR DENTAL	VISTASCAN MINI PLUS	01, 03, 09
1827/33757	DURR DENTAL	VISTASCAN MINI EASY	01, 03, 09
1827/33939	DURR DENTAL	VISTA INTRA DC	01, 03, 09
1827/33940	DURR DENTAL	VISTAPANO S	01, 03, 09
1827/33941	DURR DENTAL	VISTAPANO S CEPH	01, 03, 09
1827/35402	DURR DENTAL	VISTASCAN NANO EASY	01, 03, 09

Signed at Pretoria

Boitumelo Semete-Makokotlela

Chief Executive Officer

22 December 2023

Date

LICENCE CONDITION 01

a) The licence holder must keep a record of every transaction of this model, and such record must include the following information:

(i) Name and address of the purchaser.
(ii) Brand, model and serial number.
(iii) Date of transaction.

b) Any advertisement or other kind of promotional material may only contain the information about the **intended purpose** of this particular model that was supplied in the application form initially.

c) If SAHPRA.is associated with this model in any advertisement or in other way, the following disclaimer must be clearly displayed, along with the licence number issued to this particular model:

"This device has been licensed by SAHPRA**. The device therefore complies with SAHPRA's minimum safety requirements, but its clinical efficacy has not been evaluated."**

d) If this model is used in a medical application, the fact that it has been licensed by SAHPRA may not be used in any way by the licence holder as the basis for any claim regarding the clinical efficacy of this model.

e) This model may not be promoted or represented in any way as having been approved by SAHPRA.

f) If it comes to the notice of the licence holder or if the licence holder has reason to suspect that units of this model has a defect or a fault, the licence holder must immediately notify Radiation Control of the relevant facts. This written notification must contain the following information:

(i) Licence No, Brand and Model (as on licence)
(ii) Date on which and circumstances under which such defect or fault was discovered or first suspected
(iii) Description of the defect or fault
(iv) Evaluation of the risk of injury resulting from such defect or fault
(v) Number of units of this model that have been distributed in South Africa
(vi) Proposed plan for rectifying such defect or fault - for approval by Radiation Control
(vii) Date when execution of such plan is expected to be completed
(viii) Proposed instructions regarding the use of this model pending the rectification the defect or fault - for approval by Radiation Control

g) This licence is also subject to the provisions of the Regulations relating to Group III Hazardous Substances (Regulation R690, 14 April 1989).

Signed at Pretoria

Chief Executive Officer

22 December 2023

Date

LICENCE CONDITION 03

IF A THIRD PARTY IS USED TO PERFORM THE FINAL TRANSACTION WITH THE END-USER, THE LICENCE HOLDER IS RESPONSIBLE TO ENSURE THAT ALL PARAGRAPHS UNDER LICENCE CONDITIONS 01 AND 03 ARE ADHERED TO.

a) In the case of any diagnostic X-ray unit, therapeutic X-ray unit , electron accelerator, reporting monitor, CR reader or DDR detector:

(i) For installation and use, the licence holder must submit the appropriate **form** to SAHPRA:

RC-DEALER: Diagnostic X-ray device and related components
RC-DENT: Dental X-ray device and related components
RC003-1 and RC011-1 (rev 1): Therapy equipment

(ii) Delivery or installation of any unit/component may commence only after the licence holder has received approval ("**MAY INSTALL**") from SAHPRA:**.**

(iii) If this model is a mobile X-ray unit, the licence holder must inform the purchaser that SAHPRA: will licence mobile X-ray units exclusively for mobile diagnostic radiography.

(iv) The licence holder must ensure that the applicable acceptance tests are performed before the unit is put into clinical service. All prescribed acceptance tests must be performed by an **Inspection Body** approved by SAHPRA:, for:

- **DIAGNOSTIC** X-ray unit, component, reporting monitor, CR reader / DDR detector (**EXCLUDING** lithotriptor, bone densitometer) as set out in the document **Diagnostic QC** (latest version),

- **DENTAL** X-ray unit and related components, as set out in the document **Diagnostic QC Dental** (latest version).

The above documents are available at (www.sahpra.org.za/radiation-control).

(v) If a reporting monitor is delivered to a client or installed by the licence holder, the licence holder must ensure that the reporting monitor complies with section V (Table 4) of the document **DIAGNOSTIC QC** (latest version) which is available at www.sahpra.org.za/radiation-control

(vi) If this model is licensed as a component, the licence holder must draw up a declaration in which the licence holder states that the compatibility of this component has been verified in accordance with the manufacturers' instructions and that the licence holder has carried out the installation in accordance with these instructions. The licence holder must provide the purchaser with a copy of this declaration.

(vii) If this model is a fixed fluoroscopic X-ray unit, the licence holder must ensure that each unit sold after January 2007 is equipped with a Dose Area Product (DAP) meter or a device that provides a dose readout during fluoroscopy.

b) In case of any Class 3b or Class 4 laser:

(i) The licence holder must provide the purchaser with a copy of the latest version of the application form SBLM-1.
(ii) This model may only be supplied to the purchaser once the purchaser possesses documentary proof that the required licence to use that particular unit has been issued by SAHPRA:.
(iii) Details of the transaction involving this model must be submitted by the licence holder on form RC011(MRI) to Radiation Control within 21 days after the transaction has been finalised.

c) In case of any MRI:

(i) The licence holder must provide the purchaser with a copy of the latest version of the application form SBMR-1.
(ii) This model may only be supplied to the purchaser once the purchaser possesses documentary proof that the required licence to use that particular unit has been issued by SAHPRA:.
(iii) Details of the transaction involving this model must be submitted by the licence holder on form RC011(MRI) to Radiation Control within 21 days after the transaction has been finalised.

Signed at Pretoria

Boitumelo Semete-Makokotlela

Chief Executive Officer

22 December 2023

Date

LICENCE CONDITION 09

ANNUAL SUBMISSION OF COMPLIANCE INFORMATION

The licence holder must submit the following information by 1 May 2024 with respect to this model, using form 41BM-2:

(i) Classification according to Annex IX of EC Directive 93/42/EEC
(ii) Annex(es) employed for conformity assessment
(iii) EC Certificate No(s)
(iv) Date(s) of EC Certificate(s)
(v) Expiry Date(s) of EC Certificate(s)
(vi) Notified Body Identification No
(vii) Date of EC Declaration of Conformity by the manufacturer

Signed at Pretoria

Chief Executive Officer

22 December 2023

Date