Document Detail

Type: 0170-Regulatory Docu

Document No.: 0170-REGD-0000000002[4]

Title: ISO Certificate of Registration CE #514069

Comment:

Status: CURRENT

Effective Date: 18-Feb-2021

Approval

Owner Role	Sign-off By	Sign-off Date	
0170-QA/RA Manager TDS-QA/RA Manager	Terri Stanton	18-Feb-2021 2:35 pm	GMT
0170-Document Control TDS-Document Control	Anthony Skeans	18-Feb-2021 1:56 pm	GMT

Reference

Document No.	Title	Relation
0170-DMR-7-050 [11]	CNC Vortex Rotary Files	Related
0170-DMR-7-029 [11]	ProFile GT Rotary Files	Related
0170-DMR-7-031 [14]	ProRoot MTA	Related
0170-DMR-7-037 [13]	Absorbent Paper Points	Related
0170-DMR-7-036 [18]	Gutta Percha Points	Related

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 514069**

Issued To: **DENTSPLY Tulsa Dental Specialties**
608 Rolling Hills Drive
Johnson City
Tennessee
37604
USA

In respect of:

The design, development and manufacture of endodontic rotary files, stainless steel, titanium and plastic endodontic obturators, gutta percha core obturators, ProRoot® Mineral Trioxide Aggregate (MTA) root canal repair material, gutta percha points, and endodontic absorbent paper points.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2007-01-30** Date: **2021-02-12** Expiry Date: **2024-05-26**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 514069**
Date:	**2021-02-12**
Issued To:	**DENTSPLY Tulsa Dental Specialties** **608 Rolling Hills Drive** **Johnson City** **Tennessee** **37604** **USA**

Subcontractor:	**Service(s) supplied**
Dentsply Dental (Tianjin) Co., Ltd. H2 Hongtai Industrial Estate No. 78 Taihua Road TEDA Tianjin 300457 China	**Manufacture**
DENTSPLY Detrey GmbH De-Trey-Strasse 1 Konstanz 78467 Germany	**EU Representative**
Dentsply Indústria e Comércio Ltda. Rua José Francisco de Souza, 1926 Distrito Industrial Pirassununga São Paulo 13633-412 Brasil	**Manufacture**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 514069**
Date:	**2021-02-12**
Issued To:	**DENTSPLY Tulsa Dental Specialties** **608 Rolling Hills Drive** **Johnson City** **Tennessee** **37604** **USA**

Subcontractor:	**Service(s) supplied**
Hantech Medical Device Co., Ltd. No. 288, Sanheng Road Changhe Industrial Park, Cixi 315326 Ningbo People's Republic of China	**Manufacture**
Sterigenics US, LLC 75 Tilbury Road Salem New Jersey 08079 USA	**Radiation (Gamma Sterilization)**
Sterigenics US, LLC 1700 College Blvd West Memphis Arkansas 72301 USA	**Radiation (Gamma Sterilization)**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 514069**
Date: **2021-02-12**
Issued To: **DENTSPLY Tulsa Dental Specialties**
608 Rolling Hills Drive
Johnson City
Tennessee
37604
USA

Date	Reference Number	Action
30 January 2007		a) First Issue, transfer from SGS b) Extension to scope (addition of: sterile dental implant systems based on synthetic and natural hydroxyapatite) from Dentsply Friadent CeraMed, (certificate number CE 01973) c) Sub contractors list includes: Dentsply Friadent Ceramed as the manufacturer of Class III, Animal Tissue Devices. Dentsply Tulsa Dental Specialties-second company site; subcontractors from CE 01973, previously held by Dentsply Friadent Ceramed: Nelson Laboratories, Steris Corporation Isomedix Services, BioForm Medical Inc, Hyaluron Inc,.
21 July 2008	4919337	Addition of the following sub contractors to the significant list of sub contractors Swift & Company – Animal Substances, Supply HyClone - Animal Substances, Supply STS division of Ethox Corp. – Sterilization Dentsply Specialty Materials - Manufacture and & Animal substances
26 January 2010	7478717	Certificate renewal Subcontractors removed: Nelson Laboratories, USA Steris Corp Isomedix Services, STS division of Ethox Corp. and HyClone Addition of subcontractors: DENTSPLY Friadent GmbH, DENTSPLY De Trey GmbH for EU Reps., Sterigenics International Inc., for Gamma Sterilization and Sterigenics Queensbury for ETO Sterilization

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 514069**
Date: **2021-02-12**
Issued To: **DENTSPLY Tulsa Dental Specialties**
608 Rolling Hills Drive
Johnson City
Tennessee
37604
USA

Date	Reference Number	Action
19 October 2011	7490415	Extension of scope to include 'and natural hydroxyapatite' Addition of the following subcontractors: DENTSPLY Professional Division, 1301 Smile Way, York, PA-17404, USA' for 'manufacture' Sterigenics, Inc., 1003 Lakeside Drive, Gurnee, IL 60031, USA' for 'gamma sterilisation' Mertz Aesthetics, 4133 Courtney Road, #10, Franksville, WI 53126' for 'manufacture, packaging, steam sterilisation' DENTSPLY Friadent, Steinzeugstral:\e 50, 68229 Mannheim , Germany' for 'EU Representative' Addition of 'design' activities to significant subcontractor, DENTSPLY Tulsa Dental Specialties, 5100 East Skelly Drive, Suite 300, Tulsa, Oklahoma, USA
16 July 2012	7856438	Extension of scope to include ' Gutta Percha Core Obturators' Removal of the following subcontractors: DENTSPLY Tulsa Dental Specialties, Suit 300, 5100 East Skelly Drive, Tulsa, Oklahoma USA' for 'Design, Development, Regulatory Compliance and Sales' BioForm Medical Inc, 4133 Courtney Road, Suite # 10, Franksville, WI 53126, USA' for 'manufacture and Design' DENTSPLY Friadent, Steinzeugstral:\e 50, 68229 Mannheim, Germany for 'EU Representative'

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 514069**
Date: **2021-02-12**
Issued To: **DENTSPLY Tulsa Dental Specialties**
608 Rolling Hills Drive
Johnson City
Tennessee
37604
USA

Date	Reference Number	Action
		DENTSPLY Speciality Materials (DSM), 1311 Smile Way, York , Pennsylvania 17404, USA' for 'Manufacture' Hayluron Inc, 99 South Bedford Street, Burlington, MA 01803, USA,`for Design and Manufacture' Sterigenics International Inc, 75 Tilburn Road, Salem, NJ 08079, USA, ` for Gamma Sterilization' Sterigenics US, LLC, 84 Park Road, Queensbury, New York 12804, USA ` for ETO Sterilization' Addition of the following subcontractors: Dentsply Industria e Comercio Ltda, Petropolis, Rio de Janeiro, Brazil for Manufacture DENTSPLYDental (Tianjin) Co., Ltd, H2 Hongtai Industrial Estate, No. 78 Taihua Road, TEDA, 300457 Tianjin, China for Manufacture Correction and Change to significant subcontractor address from ` DENTSPLY DeTey Gmbh, Postfach 10 04 42, D-78404, Konstanz, Germany' To ` DENTSPLY DeTrey, De-Trey-Strasse 1, 78467, Konstanz, Germany'.
27 February 2015	8282089	Certificate Renewal.
22 February 2019	7781058	Traceable to NB 0086.
09 January 2020	3059500	Certificate Renewal. Removal of synthetic hydroxyapatite from scope.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 514069**

Date: **2021-02-12**

Issued To: **DENTSPLY Tulsa Dental Specialties**
608 Rolling Hills Drive
Johnson City
Tennessee
37604
USA

Date	Reference Number	Action
		Removal of subcontractors: Dentsply Professional, Merz Aesthetics and Sterigenics US, LLC – Gurnee. Addition of Subcontractors: Sterigenics US, LLC – Salem and Sterigenics US, LLC – West Memphis. Clarification of address for Dentsply Indústria e Comércio Ltda.
Current	3373649	Addition of the subcontractor 'Hantech Medical Device Co., Ltd. No. 288, Sanheng Road, Changhe Industrial Park, Cixi, 315326 Ningbo People's Republic of China' for manufacture.

DENTSPLY Tulsa Dental Specialties
608 Rolling Hills Drive
Johnson City
Tennessee
37604
USA

2024-01-16

Notified Body Confirmation Letter

Reference: EU2023-607/763087

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of 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

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

DENTSPLY Tulsa Dental Specialties
608 Rolling Hills Drive
Johnson City
Tennessee
37604
USA

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ProTaper Gold Paper Points	Class IIa	N/A	CE 514069, NB 2797
WaveOne Gold Paper Points	Class IIa	N/A	CE 514069, NB 2797
ProTaper Ultimate Absorbent Points F1, F2, F3, FX, FXL, F1-F3	Class IIa	N/A	CE 514069, NB 2797
ProTaper Gold Gutta Percha Points	Class IIa	N/A	CE 514069, NB 2797
WaveOne Gold Gutta Percha Points	Class IIa	N/A	CE 514069, NB 2797
ProTaper Ultimate Conform Fit Gutta-Percha Points F1, F2, F3, FX, FXL, F1-F3	Class IIa	N/A	CE 514069, NB 2797
ProRoot MTA (Mineral Trioxide Aggregate)	Class IIa	N/A	CE 514069, NB 2797
Thermafil for WaveOne Gold Obturators	Class IIa	N/A	CE 514069, NB 2797
Thermafil for ProTaper Gold Obturators	Class IIa	N/A	CE 514069, NB 2797
GuttaCore Obturators	Class IIa	N/A	CE 514069, NB 2797
GuttaCore for WaveOne Gold Obturators	Class IIa	N/A	CE 514069, NB 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	~~Choose an item.~~	N/A	N/A

Confirmation Letter Revision History

Date	Action
2024/01/16	Initial issue