Dentsply Sirona

Document Detail

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Title: X-Smart Plus_EU Declaration of Conformity

Status: CURRENT

Effective Date: 16-Sep-2020

Review

Owner Role	Actor	Sign-off Date	Sign-off By
ENDODONTICS RC Specialist	Grégory Thomas	16-Sep-2020 9:38 am (GMT)	DIHRR949

EC Declaration of Conformity

DECLARATION OF CONFORMITY

LEGAL MANFACTURER'S NAME, ADDRESS	*Maillefer Instruments Holding Sàrl* *Chemin du Verger 3* *CH-1338 Ballaigues* *Switzerland*
SINGLE REGISTRATION NUMBER (SRN)	*N/A*
AUTHORIZED REPRESENTATIVE NAME, ADDRESS	*N/A*
COMMON SPECIFICATIONS	*N/A*
NOTIFIED BODY'S NAME, ADDRESS	*BSI The Netherlands B.V.* *Say Building, John M. Keynesplein 9* *1066 EP Amsterdam* *The Netherlands*
NOTIFIED BODY IDENTIFICATION NUMBER	*CE 2797*
APPLICABLE EU LEGISLATIONS & CONFORMITY ASSESSMENT PROCEDURE	☒ MDD 93/42/EEC, Amendment 2007/47/EEC. *Class I devices: Annex VII* *Class II devices: Annex II – excluding Section 4* ☐ MDR 2017/745 ☒ Others: *Directive 2006/42/EC on machinery, Directive 2012/19/EU on WEEE*
CERTIFICATE(S) ISSUED	Certificate No / Rev.: *CE 670383*
CERTIFICATE(S) VALIDITY DATE	*08.07.2023*
TECHNICAL DOCUMENTATION DEMONSTRATING THE CONFORMITY TO THE ABOVE LEGISLATION'S REQUIREMENTS	*1000-TF_0_TFDL_000030 [08]*

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EC Declaration of Conformity

STATEMENT OF DECLARATION

THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE MANUFACTURER AND CONFORMS TO ALL APPLICABLE REGULATIONS AND COMMON SPECIFICATIONS.

NAME, FUNCTION *Frédéric Mottier, Senior Quality Assurance Manager*

PLACE, DATE OF ISSUE *Ballaigues, 16.09.2020.*

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PRODUCTS LIST

CATALOG (SKU) NUMBER & BASIC UDI-DI *(if applicable)*	PRODUCT NAME / TRADE NAME	INTENDED PURPOSE	PRODUCT NOMENCLATURE CODE	DEVICE GROUP CODE	RISK CLASS
A103200000000	*X-Smart Plus*	*Endodontic motor, with torque and speed controls, used for driving files in both reciprocating and continuous rotation mode during an endodontic procedure.*	*Z12110101*	*MD 1106*	*Class IIa / Rule 9*
A103200000006	*X-Smart Plus*		Z12110101	*MD 1106*	*Class IIa / Rule 9*
A103200000100	*X-Smart Plus - Grant Program*		Z12110101	*MD 1106*	*Class IIa / Rule 9*
A103300000000	*X-Smart Plus Contra-angle 6:1*		Z12110180	*MD 1106*	*Class IIa / Rule 9*
A103400000300	*X-Smart Plus Handpiece*		Z12110102	*MD 1106*	*Class IIa / Rule 9*
A103400000400	*X-Smart Plus Handpiece stand*	*Accessory of X-Smart Plus system used for handpiece storage.*	Z12110199	*MD 0401*	*Class I / Rule 1*

Document History:

Version	Date	Change Summary
04	*14.09.2020*	*New version of the 1000-EFM_0041 template.* *Update of X-Smart Plus DoC due to new revision of the TFDL – from rev. 06 to rev. 07 (for more details about technical file changes, please refer to the TFDL document history).*
05	*16.09.2020*	*Update of X-Smart Plus DoC due to new revision of the TFDL – from rev. 07 to rev. 08 (for more details about technical file changes, please refer to the TFDL document history).*

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1 REFERENCE DOCUMENTS

1000-ESOP_0008: Technical Documentation

2 TRAINING

RA and or RC depending re-organization

3 REVISION HISTORY

Rev.	Author	Description of change	Reason	Training required	
				Yes	No
0	YRO	First emission of the template.	NA	X	0
1	LTO	Addition of a column in the table Annex I + more details regarding the conformity assessment procedure according to each kind of MD classes.	To differentiate sterile and non-sterile products + to better identify conformity assessment procedures.	0	X
2	AOL	-Addition of "R.T.D." as a representative of "we" in the first sentence, after "We," -Suppression of the 2nd sentence "including the subsidiaries: […] Trading as Dentsply Maillefer" -Change from ISO 13485:2012 to ISO 13485:201**6** -Addition of a clarification in Annex I: "[Full product references (SKU number) have to be captured in "Product Ref." column]"	-Revision following the update of ISO 13485:2012 to ISO 13485:2016. -Suppression of Maillefer subsidiaries to avoid confusion. -Addition of clarification points	0	X
3	LTO	-1.Removing of Maillefer address, -2.Adding of TFDL Smartsolve number and version, -3.Addition of some guidelines, in red, to fill properly the document.	-1.Each company is now free to add its address, -2.To add a clear link between TFDL/Technical File version and DoC, -3.Homogenization of how to fill this document.	0	X
4	LTO	Removing the date (2003) for Directive 93/42/EEC.	Homogenization of the way to list Directives.	0	X
5	KKW	Update related inclusion of requirements to MDR and harmonization with Corporate templates	Harmonization requirement	0	X
6	LTO	-1.Addition of the section "Products list". -2.Addition of the table "Revision History". -3.Modification of the section "Common specifications" -4.Addition of the section "Technical documentation demonstrating the conformity to the above legislation's requirements"	-1.Ease of use. -2.Traceability of the changes. -3.Common specifications are a requirements from MDR (not yet issued at this date). -4.Reference to the TFDL for conformity of the product (esp. for Applicable Standards and Essential requirements/GSPR).	0	X
7	LTO	Addition of "Others" in section "Applicable EU Legislations".	To add other legislation requiring an EU declaration of conformity (acc. to article 19.2 of the MDR).	0	X
8	GTS	Addition of CND to the list of acceptable Product Nomenclature Code	CND code will be the code used for MDR	0	X

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