DECLARATION OF COMPATIBILITY

SYSTEMS AND PROCEDURE PACKS

(Regulations : (EU) 2017/745, Article 22, UK MDR 2002, section 14.)

SYSTEM/PROCEDURE PACK PRODUCER NAME, ADDRESS	**Maillefer Instruments Holding Sàrl** Chemin du Verger 3, CH-1338 Ballaigues, Switzerland
SINGLE REGISTRATION NUMBER (SRN)	**CH-PR-000022681**
AUTHORIZED REPRESENTATIVE NAME, ADDRESS	**Dentsply DeTrey GmbH** De-Trey-Straße 1, 78467 Konstanz, Germany
SINGLE REGISTRATION NUMBER (SRN)	**DE-AR-000005904**

SYSTEM / PROCEDURE PACK NAME	TruNatomy® Treatment Solution
CATALOG (SKU) NUMBER	*B00TNMYTS0KIT*
BASIC UDI-DI	*++J00310133DZ*

STATEMENT OF DECLARATION

THIS DECLARATION OF COMPATIBILITY IS ISSUED BY THE MANUFACTURER AND CONFORMS TO ALL APPLICABLE REGULATIONS AND COMMON SPECIFICATIONS.

1. The devices included in the above system or procedure pack have been subject to the relevant conformity assessment procedures by the manufacturer of the device.
2. The devices included in the above system or procedure pack are combined in a manner that is compatible with the intended purpose of the devices and within the limits specified by the manufacturer.
3. The mutual compatibility of the device, and if applicable other products, was verified in accordance with the manufacturers' instructions and activities in accordance with those instructions have been carried out
4. The system or procedure pack was packaged and supplied with relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together.
5. The activity of combining devices and, if applicable other products, in the above-mentioned system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

NAME, FUNCTION	*Frédéric Mottier - QA/RC Director*
PLACE, DATE OF ISSUE	*Bollaigues, 16.08.2022*

MAILLEFER INSTRUMENTS HOLDING SARL CH 1338 BALLAIGUES CHEMIN DU VERGER 3

Annex I: SYSTEMS / PROCEDURE PACKS content

System / Procedure Pack Name	System / Procedure Pack SKU/ Reference	Included Single Product SKU/ Reference	Included Single Product Name	Included single product class	Included single product legal manufacturer
TruNatomy® Treatment Solution	B00TNMYTS0KIT *(++J00310133DZ)*	BSTTNMY325SQC (++J00310037E4)	TruNatomy®	IIa	Maillefer Instruments Holding Sàrl, Switzerland
		BSTTNMY316OMD (++J00310037E4)	TruNatomy®	IIa	Maillefer Instruments Holding Sàrl, Switzerland
		BSTTNMY325GLR (++J00310037E4)	TruNatomy®	IIa	Maillefer Instruments Holding Sàrl, Switzerland
		BSTTNMY325SML (++J00310037E4)	TruNatomy®	IIa	Maillefer Instruments Holding Sàrl, Switzerland
		BSTTNMY325PRM (++J00310037E4)	TruNatomy®	IIa	Maillefer Instruments Holding Sàrl, Switzerland
		BSTTNMY325MED (++J00310037E4)	TruNatomy®	IIa	Maillefer Instruments Holding Sàrl, Switzerland
		B00TNGPF00AST (++J00310043DX)	TruNatomy® Conform Fit® Gutta Percha	IIa	Maillefer Instruments Holding Sàrl, Switzerland
		BSTTNPP000AST (++J00310045E3)	TruNatomy® Absorbent Points	IIa	Maillefer Instruments Holding Sàrl, Switzerland
		BNSDSIN52230G (To be defined)	Irrigation Needle	IIa	Produits Dentaires SA, Switzerland