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	X-Smart® Pro + TruNatomy® Kit
CATALOG (SKU) NUMBER	B00XSPPTN0KIT
BASIC UDI-DI	++J00310137E9

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	*Ballaigues, 05.02.2024*

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
X-Smart® Pro + TruNatomy® Kit	B00XSP0TN0KIT	6779016	X-Smart® Pro +	IIa	SIRONA Dental Systems GmbH, Germany
		B00TNMYTS0KIT	Treatment Solution Box – TruNatomy®	Procedure Pack (highest device class: IIa)	Maillefer Instruments Holding Sàrl, Switzerland
		60620115	AH Plus Jet® Starter Kit	IIa	Dentsply DeTrey GmbH, Germany

REVISION HISTORY

(Can be removed while provided externally)

REVISION LEVEL	CC/CHO REFERENCE	PREPARED BY	DESCRIPTION OF CHANGE
00	Single approval	Angélique Bolle-Maurin	Creation of this Declaration of Compatibility following CHANGE-PLN-2021-648
01	Single approval	Marie Chantebel	Correction of AH Plus Jet® Starter Kit SKU from 60620115AHPJS to 60620115.