

<b>DECLARATION OF COMPATIBILITY FOR SYSTEMS/PROCEDURE PACKS</b>					
<b>CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM</b>					
<b>RECORD NUMBER</b>	1000-TF_10_DOC_000134	<b>REVISION LEVEL</b>	1	<b>PAGE NO</b>	Page 1 of 3

## DECLARATION OF COMPATIBILITY

SYSTEMS AND PROCEDURE PACKS

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

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

SYSTEM / PROCEDURE PACK NAME	X-Smart® Pro + ProTaper Ultimate® kit
CATALOG (SKU) NUMBER	B00XSPPTLKIT
BASIC UDI-DI	++J00310136E7

## STATEMENT OF DECLARATION

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

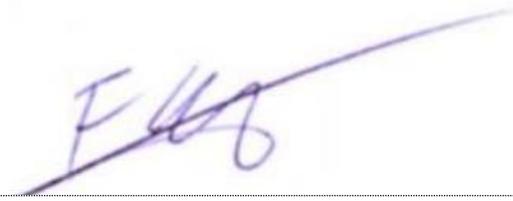
1. The devices included in the above system or procedure pack have been subject to the relevant conformity assessment procedures by the manufacturer of the device.
2. The devices included in the above system or procedure pack are combined in a manner that is compatible with the intended purpose of the 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.

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NAME, FUNCTION

*Frédéric Mottier - QA/RC Director*



PLACE, DATE OF ISSUE

*Ballaigues, 01.02.2024*

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**Annex I:** SYSTEMS / PROCEDURE PACKS content

<b>System / Procedure Pack Name</b>	<b>System / Procedure Pack SKU/ Reference</b>	<b>Included Single Product SKU/ Reference</b>	<b>Included Single Product Name</b>	<b>Included single product class</b>	<b>Included single product legal manufacturer</b>
X-Smart® Pro + ProTaper Ultimate® kit	B00XSPOPTLKIT	6779016	X-Smart® Pro +	Ila	SIRONA Dental Systems GmbH, Germany
		B00PTULTSOKIT	Treatment Solution Box – Protaper Ultimate®	Procedure Pack (highest device class: Ila)	Maillefer Instruments Holding Sàrl, Switzerland
		60620115	AH Plus Jet® Starter Kit	Ila	Dentsply DeTrey GmbH, Germany

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**REVISION HISTORY**

*(Can be removed while provided externally)*

<b>REVISION LEVEL</b>	<b>CC/CHO REFERENCE</b>	<b>PREPARED BY</b>	<b>DESCRIPTION OF CHANGE</b>
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.