Manufacturer:	Dentsply LLC 1301 Smile Way, York, PA 17404 USA Single registration number (SRN): US-MF-000022592
Authorized EU-representative:	Dentsply De Trey GmbH De-Trey-Stra0e 1 D-78467 Konstanz Germany Single Registration Number (SRN): DE-AR-000005904
Authorized UK-representative:	N/A

PRODUCT CODE / CATALOGUE NUMBER	NAME
644431	SmartLite Pro EndoActivator™ Complete Kit
644432	SmartLite Pro EndoActivator™ Refill Kit
644435	SmartLite Pro EndoActivator™ 25 Tips Small
644436	SmartLite Pro EndoActivator™ 25 Tips Medium
644437	SmartLite Pro EndoActivator™ 25 Tips Medium Long
644438	SmartLite Pro EndoActivator™ Attachment

Classification and Rules (EU and UK)	Class IIa per Rule 9 and 5 of Annex VIII of MDR 2017/745 • Active device • Transient invasive use connected to an active device
Basic UDI-DI :	++D001ENDOACTIVATORG8
EMDN code / description :	Q01090-Dental devices - various
GMDN code / description :	Tips: 63814 Root canal ultrasonic irrigation handpiece tip Attachment: 43938 Solution agitator
Intended purpose:	The SmartLite Pro EndoActivator™ Endodontic Activation System is used in endodontic treatment by application of sonic energy. The SmartLite Pro EndoActivator™ Activator Tips are used in conjunction with the SmartLite Pro EndoActivator™ Attachment mounted on the SmartLite Pro EndoActivator™ handpiece to provide the energy for tip oscillation and vibration.

WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF
- THE REGULATION EU/2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX IX.

ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

External references applied	Refer to 0060-TEC-LAER-115
EC Certificate	EC certificate number: MDR 753349 BSI Group the Netherlands Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands Notified Body identification number 2797
UK Certificate	N/A
Reference to the corresponding Technical Documentation	Technical Documentation name: SmartLite Pro EndoActivator™ Endodontic Activation System Technical Documentation Index: 0060-TEC-INDEX-115

1301 Smile Way, York, PA 17404 USA

Effective Date: 22MAR2023

Khyati Dave
Quality and Regulatory Affairs Director
Signing as representative PRRC for legal manufacturer

Jonathan Coleman
Quality and Regulatory Senior Manager
Signing as representative PRRC for legal manufacturer

REVISION HISTORY

REVISION LEVEL	CC/CHO REFERENCE	PREPARED BY	DESCRIPTION OF CHANGE
0	CHO-2023-52147	M. Curti	Initial release of MDR DOC