Dentsply Sirona Restorative

DECLARATION OF CONFORMITY ACCORDING TO THE DIRECTIVE 93/42/EEC

Manufacturer:	Dentsply LLC, also trading as DENTSPLY Caulk 38 West Clarke Avenue, Milford DE 19963 USA		
Design Holder:	Dentsply LLC, also trading as DENTSPLY Caulk 38 West Clarke Avenue, Milford DE 19963 USA		
Authorized EU-Representative:	DENTSPLY DeTrey GmbH, DeTrey Strasse 1, Konstanz Germany D-78467		
Unique Product Identification:	**NAME**	**Classification**	**Rule**
644400	SmartLite® Pro Introductory Kit	I	12
644409	SmartLite® Pro Basic Kit	I	12
644401	SmartLite® Pro Battery Refill	I	12
644402	SmartLite® Pro Sleeves Refill	I	12
644403	SmartLite® Pro Eye Protection Shields Refill	I	12
644404	SmartLite® Pro Power Connector Refill	I	12
644405	SmartLite® Pro Transillumination Tip Refill	I	12
644406	SmartLite® Pro PolyCure Tip Refill	I	12
644407	SmartLite® Pro Bluelight Tip Refill	I	12
644408	SmartLite® Pro O-Rings Refill	I	12
GMDN Code :	35775 Dental/surgical polymerization lamp		
Classification Rules according to:	This product is classified as a Class I Medical Device under Annex IX Section III, rule 12, transient, active device.		
We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC amended by 2007/47/EC for medical devices, in accordance with the Annex I. All supporting documentation is retained under the premises of the manufacturer. The manufacturer is exclusively responsible for the Declaration of Conformity.			
Harmonized Standards applied:	Dentsply LLC, also trading as DENTSPLY Caulk maintains a quality management system that complies with the United States Food and Drug Administration 21 CFR Part 820 & 211, ISO 13485:2016, CMDR, PMDA (MO 169), ANVISA, TGA, and the European Union Council Directive 93/42/EEC.		
Technical Standards referenced:	N/A		
EC Certificate:	This declaration is made on the basis of the Certificate of Conformity CE 668748 issued by issued by BSI Assurance UK Limited 389 Chiswick High Road London W4 4AL, UK with Notified Body identification number 0086 in accordance with Annex II excluding section 4 of the Directive.		

Dentsply LLC, also trading as
DENTSPLY Caulk
38 West Clarke Avenue
Milford DE 19963
USA

Karen Trovalli March 15, 2019

Karen Trovalli
QA/RA Manager

Date

Title: Declaration of Conformity
SmartLite® Pro Modular LED Curing Light
Dept/Owner: Research & Development/ VP R&D Global Restorative SBU

REVISION HISTORY

Rev #	Revision Originator	DESCRIPTION
0	T. Diamond Cartwright	Created DOC for SmartLite® Pro user evaluation in Europe. No PCO required.
1	T. Diamond Cartwright	Revised DOC from user evaluation to marketed product. Updated the rule associated with product. Removed item K344400. Included additional packages 644400-644409. No PCO required.