Document Detail

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Title: SmartLite Pro Modular LED Curing Light Declaration of Conformity

Comment:

Status: CURRENT

Effective Date: 02-Nov-2023

Approval

Owner Role	Sign-off By	Sign-off Date	
0070-Document Control Milford Document Control	Michelle Wilson	02-Nov-2023 3:13 pm	GMT
0070-RA Approver Milford Regulatory Affairs Approver	Stacia Preston	02-Nov-2023 6:23 pm	GMT

Manufacturer:	Dentsply LLC, also trading as DENTSPLY Caulk 38 West Clarke Avenue, Milford DE 19963 USA Single Registration Number (SRN): US-MF-000016555
Authorized EU-representative:	Dentsply DeTrey GmbH De-Trey-Strasse 1, 78467 Konstanz, Germany Single Registration Number (SRN): DE-AR-000005904
Authorized UK-representative:	N/A
PRODUCT CODE / CATALOGUE NUMBER	**NAME**
644400	SmartLite® Pro Modular LED Curing Light Introductory Kit
644401	SmartLite® Pro Rechargeable Battery Pack
644402	SmartLite® Pro Sleeves Refill
644403	SmartLite® Pro Eye Protection Shields Refill
644404	SmartLite® Pro Power Connector Refill
644405	SmartLite® Pro Transillumination Tip Refill
644406	SmartLite® Pro PolyCure™ Tip Refill
644407	SmartLite® Pro Cure Tip Refill
644408	SmartLite® Pro O-Ring Refill
644409	SmartLite® Pro Modular LED Curing Light Basic Kit
Classification and Rules (EU and UK)	EU Class: Class I following Rule 13, transient, active device. ACCORDING TO ANNEX VIII OF THE REGULATION 2017/745 UK Class: N/A ACCORDING TO ANNEX IX OF THE DIRECTIVE 93/42/EC AND UK MDR 2002
Basic UDI-DI	++D002CURINGLITESAT
EMDN code / description	Z12119003 - Cold Light Dental Equipment
GMDN code / description	35775 - Dental/surgical polymerization lamp 12535 - Medical equipment drape, single-use (barrier sleeve)
Intended purpose	SmartLite® Pro Modular LED Curing Light is indicated for light activated polymerization of dental materials such as composites, luting cements, and sealants using visible light and for intraoral illumination used upon initial examination of the dental patient and dental transillumination to help locate crown fractures, posterior and anterior caries, and for use as an auxiliary light source for endodontic procedures.

WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF

- THE REGULATIONS EU/2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEXES II AND III.
- THE MEDICAL DEVICE REGULATIONS 2002 (SI 618) as subsequently amended by the EU EXIT REGULATIONS OF 2019 (SI 791) and 2020 (SI 1478).

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

External references (Common Specifications, Standards, Regulations) applied	TF089-LAER
EC Certificate	N/A
UK Certificate	N/A
Reference to the corresponding Technical Documentation	TF089

Dentsply LLC, also trading as
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SPreston 11/1/23

Stacia Preston — Date
Regulatory Compliance Manager