



DECLARATION OF CONFORMITY CRSCAM TEKNOLOJİ A.Ş.

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WE DECLARE THAT THE PRODUCTS LISTED AS CRSCAM TEKNOLOJİ A.Ş. WITH THE REQUIREMENTS FOR THE MEDICAL DEVICES DECISION 2017/745/EU OF THE INSTRUCTIONS BOARD. ALL SUPPORTING DOCUMENTS ARE AVAILABLE AT THE MANUFACTURER'S FACILITIES.

AS CRSCAM TEKNOLOJİ A.Ş., WE DECLARE TO FOLLOW THE OBLIGATIONS OF THE APPROVED QUALITY SYSTEM AND TO PROTECT THE APPROVED QUALITY AND KEEP THE APPROVED QUALITY SYSTEM SUFFICIENT AND EFFECTIVE.

THIS DOCUMENT HAS BEEN PREPARED IN ACCORDANCE WITH ANNEX IV OF THE MEDICAL DEVICE REGULATION 2017/745.

Product Name/Trade Name : Composite Resin
Classification : 2017/745 Medical Device Regulation -Annex VIII, Rule 7, Class IIa, Non-sterile
Conformity Assessment Route : MDR 2017/745 Annex IX Chapter I

GMDN CODE : 31783- Crown/bridge
Brand : Custom Resin Solutions
CND Kod : Q010205
SRN No : TR-MF-000038684
Basic UDI-DI : 8684313961DD_CBDF
Intended Use : Composite resin is a specialty methacrylate-based 3D printer resin for printing natural dental aesthetics. It has been specially developed to be biocompatible and have high flexural strength for dental applications. Composite Resin can be used for 3D printers with any type of DLP or LCD technology. Composite Resin is used in DLP/LCD curing 3D printers to produce temporary crowns and bridges to be used inside the mouth.

CRSCAM TECHNOLOGY A.Ş. HAS DEVELOPED AND CONTINUES TO MAINTAIN A DOCUMENTED POST-MARKET SURVEILLANCE PROCESS, INCLUDING REPORTING OF REPORTABLE INCIDENTS UNDER THE SCOPE OF THE EUROPEAN MEDICAL DEVICES CONFORMITY ASSESSMENT SYSTEM GUIDES, TO THE COMPETENT AUTHORITIES.

THE PRODUCTS HAVE BEEN ASSESSED BY A NOTIFIED BODY FOR CONFORMITY AND HAVE BEEN GRANTED A CE CERTIFICATE.



List of Products:

Ref No	Product Volume	Product Name	UDI-DI
DD_CBL_003	250 ml	Composite Resin- B1	8684313961023
DD_CBL_002	500 ml	Composite Resin- B1	8684313961016
DD_CBL_001	1000 ml	Composite Resin- B1	8684313961009
DD_CBB_003	250 ml	Composite Resin- 1M1	8684313961030
DD_CBB_002	500 ml	Composite Resin- 1M1	8684313961047
DD_CBB_001	1000 ml	Composite Resin- 1M1	8684313961054
DD_CBA_003	250 ml	Composite Resin -A2	8684313961061
DD_CBA_002	500 ml	Composite Resin- A2	8684313961078
DD_CBA_001	1000 ml	Composite Resin- A2	8684313961085
DD_CBC_001	1000 ml	Composite Resin- A1	8684313961092
DD_CBC_002	500 ml	Composite Resin- A1	8684313961108
DD_CBC_003	250 ml	Composite Resin- A1	8684313961115
DD_CBD_001	1000 ml	Composite Resin-C1	8684313961122
DD_CBD_002	500 ml	Composite Resin- C1	8684313961139
DD_CBD_003	250 ml	Composite Resin- C1	8684313961146
DD_CBF_001	1000 ml	Composite Resin- C2	8684313961153
DD_CBF_002	500 ml	Composite Resin -C2	8684313961160
DD_CBF_003	250 ml	Composite Resin- C2	8684313961177

RELATED STANDARDS:



EN ISO 13485:2016	MDR 2017/745/EU
EN ISO 15223-1:2021	ISO 10993-6:2016
EN ISO 10993-1:2018	EN ISO 10993-18:2009
EN ISO 10993-5:2009	EN ISO 10993-10:2021
EN ISO 14971:2019	ISO 10477:2020
ISO 10993-11:2017	MEDDEV 2.7/4 :2010
MEDDEV 2.12/1 rev. 8 :2013	MEDDEV 2.12/2 rev.2 :2012
ASTM F1980 – 21:2021	MEDDEV 2.7/1 rev.4 :2016
IEC 62366-1:2015/Amd 1:2020	MDCG 2020-8
MDCG 2020-7	MDCG 2020-6
MDCG 2020-5	MEDDEV 2.7/2
MEDDEV 2.4/1	EN ISO 14155:2020
EN 20417:2021	MDCG 2021-24
MDCG 2020-13	MDCG 2022-21

Notified Body. : UDEM Adriatic d.o.o
Notified Body No : 2696
Notified Body Address : Radnička cesta 54/ R3, Green Gold Centar, IV. kat. Zagreb
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General Manager

Stamp /Signature / Date

GÜLGÜN SATICI KARACA

12.03.2024

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