



DECLARATION OF CONFORMITY

Document Number	TD-02-14.01
Broadcasting Date	07.10.2019
Revision Number	00
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MANUFACTURER İNCİ DENTAL TIBBİ MALZEME SAN. AND TRADE LTD. ŞTİ.

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CLASSIFICATION MDD 93/42/EEC Medical Device Directive - ANNEX IX .

Product	Class	Rule
CAVITY LINER	Ila	8
EDTA	Ila	6
FIBER POST	Ila	8
CALCIUM HYDROXIDE	Ila	7

CONFORMITY ASSESSMENT MDD 93/42/EEC Medical Device Directive - ANNEX V-Manufacturing Quality Assurance

NAME OF THE PRODUCT DENTAL PROTECTIVE MATERIALS

BRAND NAME RUBY

MODELS MODELS TD-02-02.LS-01 is given in the Product List.

Product	GMDN Code	GMDN Name	GMDN Description
CAVITY LINER	38649	Dental Filling, Polymer essential	Polymer-based made of material (resin) fixed, custom-made, intracoronal restoration. CATEGORIES: 03-Dental Devices 10- Disposable Devices TYPE: APPLICABLE TERM
EDTA	34524	Dental solution, cleaner	Preparation after that bruises or root channels are cleaned using One liquid. rot or root channel disinfect to do or to dry It can also be used for.
FIBER POST	38609	Root Channel Post, Previously made	Prepared One root to the channel hold or support by snuggling about designed One prefabricated direct or rod. Prefabricated poles of strange shapes and dimensions with alloy, ceramic, or fiber reinforced from polymers are being done. CATEGORIES: 03 dental devices TYPE: APPLICABLE TERM.
CALCIUM HYDROXIDE	47232	Calcium hydroxide suspension	External Latest addition in medicine from the process before root channels and crowns/bridges wash and disinfect including to be about various for purposes used A lot basic (high pH) a calcium hydroxide (Ca (OH)2) solution (slaked lime or lime milk also known as) and temporary One external filling of the material viscosity to change and/or is to moisturize. Produce reparative dentin for fibroblasts (of the body) bond its texture constituent cells) odontoblast- like cells also encourage the transformation. From the app later This device again cannot be used.

İNCİ DENTAL TIBBİ MALZEME SAN. AND TRADE LTD. ŞTİ. WE DECLARE THAT THE LISTED PRODUCTS COMPLY WITH THE REQUIREMENTS OF THE MEDICAL DEVICES DIRECTIVE 93/42/EC. ALL SUPPORTING DOCUMENTATION IS AVAILABLE AT THE MANUFACTURER'S PREMISES.

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İNCİ DENTAL TIBBİ MALZEME SAN. AND TRADE LTD. ŞTİ. WE DECLARE TO FULFILL THE OBLIGATIONS IMPOSED BY THE APPROVED QUALITY SYSTEM AND TO MAINTAIN THE APPROVED QUALITY AND TO KEEP THE APPROVED QUALITY SYSTEM ADEQUATE AND EFFECTIVE.

RELEVANT STANDARDS:

EN ISO 13485:2016	EN ISO 7405:2018
EN ISO 15223-1:2016	EN ISO 10993-5:2009
EN ISO 14971:2012	EN ISO 10993-10:2010
MDD/93/42/EEC	
EN 1041:2008	
EN ISO 1641:2011	
EN ISO 10993-1:2018	

APPROVED BODY : UDEM International Certification Audit Education Central San. and Tic. Ltd. Ltd. _

APPROVED ORGANIZATION NUMBER : 2292

CE DOCUMENT PUBLICATION DATE : 06.07.2020

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CERTIFICATE NUMBER : M.2020.106.13709

CE MARK START DATE : 06.07.2020

CITY, REGULATION DATE : ISTANBUL / 07.06.2021

APPROVED BY : MEHMET EMİN DEMİR
GENERAL MANAGER

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Tıbbi Malz. San. ve Tic. Ltd. Şti.
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Bayrampaşa V.D.: 478 001 92 53
Mersis No: 0478001925300010
Ticaret Sicil No: 318673

Annex-1 of TD-02-02.LS-01

RUBYEDTA 3ML (EDTA GEL FOR ROOT CANAL TREATMENT)	8065
RUBYEDTA 3ML X 2 (EDTA GEL FOR ROOT CANAL TREATMENT)	8069
ENDOART EDTA 250ML (EDTA SOLUTION FOR ROOT CANAL TREATMENT)	8073
RUBYLINER 2 gr (LIGHT-CURING GLASS-IONOMER CEMENT)	8000
RUBYLINER 2 gr X 2 SYRINGE (LIGHT-CURING GLASS IONOMER CEMENT)	8001
RUBYLINER 2 gr X 4 SYRINGE (LIGHT-CURING GLASS IONOMER CEMENT)	8002
RUBYCAL 2 gr (CALCIUM HYDROXIDE PASTE WITH BARIUM SULFATE)	8036
RUBYCAL 2 gr X 4 (CALCIUM HYDROXIDE PASTE WITH BARIUM SULFATE)	8037
RUBYCAL 2 gr (CALCIUM HYDROXIDE PASTE WITH IODOFORM)	8038
RUBYCAL 2 gr X 4 (CALCIUM HYDROXIDE PASTE WITH IODOFORM)	8039
RUBYCAL LC 2 gr (LIGHT-CURING CALCIUM HYDROXIDE)	8052
RUBYCAL LC 2 gr X 2 SYRINGE	8053
RUBYCAL LC 2 gr X 4 SYRINGE (LIGHT-CURING CALCIUM HYDROXIDE)	8054
ENDOART FIBER POST (20PCS) X 4 PCS DRILL	7000
ENDOART FIBER POST (10 PIECES)	7018
ENDOART FIBER POST (5 PIECES)	7016

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