



MEDIT

Declaration of Conformity

Manufacturer	Medit Corp. 23 Goryeodae-ro 22-gil, Seongbuk-gu, Seoul, 02855, Rep. of Korea Tel +82-2-2193-9600
Manufacturer SRN	KR-MF-000007132
EC Representative	MERIDIUS MEDICAL EUROPE LIMITED Unit 3D, North Point House, North point Business Park, New Mallow Road CORK, T23AT2P, Ireland Tel +353 212066448
Description of Device	3D Scanner
Model(Trade) Name	MD-ID0400 (T710), MD-ID0420 (T510,T310)
Basic UDI-DI	MD-ID0400 : 88000267MD-ID0400EQ MD-ID0420 : 88000267MD-ID0420EW
EC Regulation	Medical Device Regulation (EU) 2017/745
GMDN code	38597
Classification	Class I, according to the rules 13 in Annex VIII

Standards applied

IEC 60601-1:2005, COR1:2006 + COR2:2007 + AMD1:2012
IEC 60601-1-2:2014
IEC 62366:2007 + AMD1:2014
IEC 62471:2006
IEC 62304:2006
ISO 14971:2012

The declaration of conformity is issued under the sole responsibility of the Medit Corp.
We herewith declare that the above-mentioned products meet the provisions of Medical Device Regulation (EU) 2017/745

Date of issue Jun 11, 2021

Signature GB KO / CEO

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AUTHORIZED SIGNATURE