Declaration of Conformity

Manufacturer	Medit Corp. F9, F10, 8, Yangpyeong-ro 25-gil, Yeongdeungpo-gu, Seoul, 07207, Rep. of Korea Tel +82-2-2193-9600
Manufacturer SRN	KR-MF-000007132
EC Representative	Meditrial Srl Via Po 9 00198, Rome Italy Tel +39 06 45429780 ecrep@meditrial.eu
Description of Device Brand(Trade) Name Model	Intraoral Scanner i700, i600 MD-IS0200, MD-IS0100
Intended Use	The i700 & i600 systems are a dental 3D scanner intended to be used to digitally record topographical characteristics of teeth and surrounding tissues. The systems produce 3D scans for use in computer assisted design and manufacturing of dental restorations.
Basic UDI-DI	88000267MD-IS0200KK, 88000267MD-IS0100KE
EC Regulation	Medical Device Regulation (EU) 2017/745
GMDN code	63669
Classification	Class I, according to the rules 13 in Annex VIII
Conformity assessment route	EC conformity declaration according to Annex II and Annex III of the Regulation MDR 2017/745

Standards applied

EN 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012
EN 60601-1-2:2014
EN ISO 10993-5:2009, 10993-10:2013, 10993-11:2018
EN 62366:2008
EN 62304:2006
EN ISO 14971:2012

This declaration of conformity is issued under the sole responsibility of Medit Corp.
We hereby declare that he medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by BSI Group. All supporting documentation is retained at the premises of the manufacturer.

Date of issue : MAR 03, 2022
Name : GYU BUM, KO
Title : CEO

Signature

MEDIT CORP.
AUTHORIZED SIGNATURE