



## 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	Intraoral Scanner
Brand(Trade) Name	i700
Model	MD-IS0200
Intended Use	The i700 system is a dental 3D scanner intended to be used to digitally record topographical characteristics of teeth and surrounding tissues. The i700 system produces 3D scans for use in computer assisted design and manufacturing of dental restorations.
Basic UDI-DI	88000267MD-IS0200KK
EC Regulation	Medical Device Regulation (EU) 2017/745
GMDN code	38597
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 the 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 : Aug 02, 2021

Signature

Name : GYU BUM, KO

Title : CEO

MEDIT CORP.

AUTHORIZED SIGNATURE