EU Declaration of Conformity

We Medit Corp., declare under our sole responsibility for the products mentioned below, in accordance with the Declaration of conformity of Medical Devices Regulation (EU) 2017/745.

Manufacturer	Name	Medit Corp.
	SRN	KR-MF-000007132
	Address	9F,10F,13F,14F,16F, 8, Yangpyeong-ro 25-gil, Yeongdeungpo-gu, Seoul, 07207, Republic of Korea Tel +82-2-2193-9600
Responsible Person (PRRC) or designee	Name	Jieun Eom
	Title	RA&QS Specialist
EU Authorised Representative	Name	Meditrial Srl
	SRN	IT-AR-000007805
	Address	Via Po 9 00198, Rome Italy Tel +39 06 45429780
Notified Body	Name	Not Applicable
	Identification Number	Not Applicable
Product	Name	i700 wireless system
Intended Purpose	The i700 wireless system is an intraoral 3D scanner intended to record the topographical characteristics of teeth and surrounding tissues digitally. The i700 wireless system produces 3D scans for computer-assisted design and manufacturing of dental restorations.	
EC Regulation	Medical Device Regulation (EU) 2017/745	
Classification	Class I, according to the rules 13 and 5 in Annex VIII MDR (EU) 2017/745 (See Table i700 wireless System for classification of specific components and accessories)	
EC Certificate	N/A, Self-Declared	
Conformity assessment route	EC conformity declaration according to Annex II and Annex III of the Regulation MDR 2017/745	
QMS Certificate	No.	MD 715254
	Expiry Date	24 Oct 2024
	Notified Body	BSI Group

Harmonized Standards applied

1) Safety & EMC : IEC 60601-1:2005+A1:2013+A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
2) Biocompatibility : ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity, EN ISO 10993-10:2023 Biological evaluation of medical devices - Part 10: Tests for skin sensitization, EN ISO 10993-11: Tests for systemic toxicity, EN ISO 10993-23:2021 Biological evaluation of medical devices Part 23: Tests for irritation
3) Software : IEC 62304:2006+A1:2015 Medical device software — Software life cycle processes
4) Usability : IEC 62366-1:2015+A1:2020 Medical devices Part 1: Application of usability engineering to medical devices

* Specifications used for conformity assessment are listed in the Technical Documentation

i700 wireless System				
Model Name	**Item Name**	**Classification**	**Basic UDI-DI**	**EMDN/CND Code**
MD-IS0300	Intraoral Scanner i700 wireless	Class I (Rule 13)	88000267MD-IS0300KQ	Q0199
MD-RT0300	Reusable Tip	Class I (Rule 5)	88000267MD-RT0300PQ	Z12119080
MD-RT0400	Small Tip		88000267MD-RT0400PV	
MD-IS0200CT	Calibration Tool	Class I (Rule 13)	88000267MD-IS0200CTBC	Z12119080
MD-IS0300ACT	Auto Calibration Tool		88000267MD-IS0300ACTSB	
MD-WH0300	Wireless Hub	-	--	
-	Handpiece Cover			
-	Handle Fit Cradle			
-	Monitor Mount			
-	Battery Charger			
-	Handle			
-	Practice Model			
-	Wrist Strap			
-	Desktop Cradle			
-	Wall Mount Holder			
-	USB 3.0 Cable (C to A)			
-	Power Delivery Cable (C to C)			
-	Medical Adapter for Wireless Hub			
-	Medical Adapter for Battery Charger			
-	Power Cord			
-	USB Flash Drive			

Approval :

Signed for and on behalf of Medit Corp.

Name	Jieun Hwang	Signature	
Title	RA&QS Team Leader		
Place Issued	Seoul, Republic of Korea		
Date Issued	07-Aug-2024		

<Reference>

EMDN	Term
Q0199	DENTAL DEVICES - OTHERS
Z12119080	VARIOUS ODONTOSTOMATOLOGY INSTRUMENTS - HARDWARE

Revision History

Rev	Rev. Date	Effective Date	Reason for Revision
0	03-Jan-2022	03-Jan-2022	Initial
1	03-Mar-2022	03-Mar-2022	Change GMDN Code (38597→ 63669)
2	12-May-2022	12-May-2022	Add wireless equipment and service Standard (EN 301 489-1 etc.)
3	01-Jun-2022	01-Jun-2022	Change signature date
4	10-Aug-2022	10-Aug-2022	Change of Classification Rule according to EAR Opinion (Rule 13→ Rule 10)
5	24-Oct-2022	24-Oct-2022	Change of Classification Rule according to EAR Opinion (Rule 10→ Rule 13)
6	02-Jan-2023	02-Jan-2023	Update standard applied
7	11-Jan-2023	11-Jan-2023	Add Product Components
8	31-Jan-2023	31-Jan-2023	Change address, modify to the involved use model name
9	15-Mar-2023	15-Mar-2023	Change of reusable Tip Basic UDI
10	05-July-2023	05-July-2023	Add Hub Package
11	15-Apr-2024	15-Apr-2024	Add Manufacturer SRN
12	23-Jul-2024	23-Jul-2024	Changes due to document format
13	07-Aug-2024	07-Aug-2024	Change the harmonization standard year

ME-DoC-7024_Declaration of Conformity_Rev.13

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