



Declaration of Conformity

Manufacturer	Medit Corp. (SRN: KR-MF-000007132) 9F,10F,13F,14F,16F, 8, Yangpyeong-ro 25-gil, Yeongdeungpo-gu, Seoul, 07207, Republic of Korea Tel +82-2-2193-9600
EC Representative	Meditrial Srl (SRN: IT-AR-000007805) Via Po 9 00198, Rome Italy Tel +39 06 45429780 ecrep@meditrial.eu
Description of Device Brand(Trade) Name Model	Intraoral Scanner i900 MO1-i900
Intended Use	The MO1-i900 system is a dental 3D scanner intended to be used to digitally record topographical characteristics of teeth and surrounding tissues. The MO1-i900 system produces 3D scans for use in computer assisted design and manufacturing of dental restorations.
Basic UDI-DI	88000267MO1-i900FD
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 60601-1:2006+A1:2013+A2:2021

EN 60601-1-2:2015+A1:2021

EN ISO 10993-5:2009, 10993-10:2013, 10993-11:2018, 10993-23:2021

EN 62366-1:2015EN 62304:2006+A1:2015

EN ISO 14971:2019

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: 13 Feb, 2024

Name: Jieun Hwang

Title: Market Access Team Leader

Signature

Attachment 1 Product Component

Model Name		Item Name	Basic UDI-DI	Remark
Component		MO1-i900	Intraoral Scanner i900	88000267MO1-i900FD
		MO1-HC1	Handpiece Cover	
		MO1-RTP	Reusable Tip Package	88000267MO1-RTPDR
	↳	MO1-RTM	Reusable Tip (Large)	
	↳	MO1-RTL	Reusable Tip (Normal)	
		MO1-RTS	Reusable Tip (Small)	88000267MO1-RTSDX Sold Separately
		MO1-CT1	Calibration Tool	
		MO1-WH1	Wall Mount Holder	
		MO1-DC	Desktop Cradle	
			Practice Model	
			USB Flash Drive	
			Power Delivery Cable (2m)	
			Power Delivery Cable (2.5m)	