

EC Declaration of Conformity

MANUFACTURER			
Name of Company	SRN number	Address	Single Authorized Representative
Huvitz Co.,Ltd.	KR-MF-000015802	38, Burim-ro 170beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, 14055, Republic of Korea	Chang Soo, Lee

AUTHORIZED REPRESENTATIVE		
Name of Company	SRN number	Address
Medical Device Safety Service GmbH	DE-AR-000005430	Schiffgraben 41, 30175 Hannover, Germany

We, the manufacturer, herewith declare that the products

PRODUCT IDENTIFICATION			
Product Name	Model	GMDN Code	Basic UDI Number
Non-Contact Tonometer	Non-Contact Tonometer HNT-1 Non-Contact Tono/Pachymeter HNT-1P	16809	88000196NT001G4
Intended Use: The Non-Contact Tonometer HNT-1 is intended to be used to measure the intraocular pressure of the human eye. HNT-1P is also provided measurement of patient's central corneal thickness, as well as HNT-1's function.			

The Device covered by the present EU declaration is in conformity with the (EU) MDR 2017/745 and the (EU) 2011/65

The medical device has been assigned to Class IIa according to Annex VIII (Rule 10). It bears the mark



The product concerned has been manufactured under a quality management system according to Annex IX Chapter I Section 2 and Section 3 of the Medical Device Regulation 2017/745.

Compliance of the designated product with the Medical Device Regulation 2017/745 has been assessed and certified by the Notified Body

Notified Body	Lot/Serial Number
TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431, Nürnberg, Germany/0197	HNT-1: Start from 1NT00024E0001 and after HNT-1P: Start from 1NT00P24E0001 and after

following the procedure relating to the EC Declaration of Conformity set out in Annex IX Chapter I Section 2, Section 3 and Chapter II Section 4 of the Medical Device Regulation 2017/745.

This Declaration of conformity is valid in connection with the release document.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

This declaration of conformity is issued under the sole responsibility of

Huvitz Co.,Ltd.

38, Burim-ro 170beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, 14055, Republic of Korea

TITLE: Quality Management Rep.

SIGNATURE: Lee Chang Soo

DATE: 2022.11.29