

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
MDSS GmbH	DE-AR-000005430	Schiffgraben 41, 30175 Hannover, Germany

We, the manufacturer, herewith declare that the product

PRODUCT IDENTIFICATION			
General Product group	Product Name	UMDNS Number	Basic UDI Number
Non-contact tonometers	Auto Tono/Refracto/Kerato/Pachymeter, HTR-1A	16809	08800019600558

meets provisions of the Medical Device Directive 93/42/EEC, the Electromagnetic Compatibility Directive 2014/30/EU and the RoHS directive 2011/65/EU which apply to them.

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



The product concerned has been manufactured under a quality management system according to Annex II excluding section 4 of the Medical Device Directive 93/42/EEC.

Compliance of the designated product with the Medical Device Directive 93/42/EEC 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	Start from 1TR00020H0001~ and after



following the procedure relating to the EC Declaration of Conformity set out in Annex II excluding section 4 of the Medical Device Directive 93/42/EEC .

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.

The above mentioned declaration of conformity is exclusively under the 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: Chang-Soo, Lee

DATE: 2023. 06. 30

Place of Issue: Anyang-si, Gyeonggi-do