

## 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 products

PRODUCT IDENTIFICATION			
Product Name	Model	UMDNS Number	Basic UDI Number
Auto Ref/Keratometer	Auto Ref/Keratometer	13313	08800019600138
	HRK-7000, HRK-7000A, ERK-9100		08800019600145
			08800019600503

meet the provisions of the Medical Device Directive 93/42/EEC which apply to them.

The medical device has been assigned to Class I with a measuring function according to Annex IX (Rule 12) of the Medical Device Directive 93/42/EEC. 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	HRK-7000A: Start from 7HA0AT19L001~ and after HRK-7000: Start from 7HA00019L001~and after ERK-9100: Start from 9RK00019L001~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