

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 product

PRODUCT IDENTIFICATION			
Product Name	Model	GMDN Code	Basic UDI Number
Auto Ref/Keratometer	HRK-9000A	36386, 12811	88000196RK001FH
<ul style="list-style-type: none"> Intended Use: Auto Ref/Keratometer HRK-9000A is intended to provide the information of Spherical, Cylindrical and Axis while measuring the refraction of examinee's eyes 			

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 Im according to Annex VIII (Rule 13) of the Medical Device Regulation 2017/745. It bears the mark

CE 0197



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	Start from 9HA24E0001~ 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.

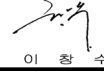
This declaration of conformity is issued under the sole responsibility of

Huvitz Co.,Ltd.

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

TITLE: Quality Management Rep.

SIGNATURE: _____


이 창 수

DATE: 2022.09.30

