

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 (MDR 2017/745)		
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/Number	UMDNS Number	Basic UDI Number
Digital Refractor	HDR-9000	13313	08800019600213

Intended use: The HUVITZ Digital Refractor HDR-9000 system is a computerized auto refractor used for subjective refraction by regarding the patient's accommodation power and facilities. Also the Digital Refractor is used for detecting and measuring any anomalies in binocular vision such as muscle balance, binocular balance, aniseikonia, fusion, and stereopsis.

meet the provisions of the Medical Device Regulation 2017/745, the RoHS directive 2011/65/EU and the Radio Equipment Directive 2014/53/EU.

The medical device has been assigned to Class I according to Annex VIII (Rule 13) of the Medical Device Regulation 2017/745. It bears the mark



The product concerned has been manufactured under a quality management system according to ISO 13485:2016, Annex IX Chapter I Section 2, Section 3 and Annex IV Section 2 of the Medical Device Regulation 2017/745.



This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

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
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