

## 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 (MDR 2017/745)			
Product Name	Model/Number	UMDNS Number	Basic UDI Number
Projectors, Chart, Eye	HCP-7000	16890	08800019600237
Intended use: HCP-7000 is an automatic chart projector which provides 41 different charts including red/green and polarized filters for the eye optometry. Also it can execute the binocular balance tests, stereo tests, fixation disparity tests, fusion tests and aniseikonia tests.			

meets provisions of the Medical Device Regulation 2017/745 and the RoHS directive 2011/65/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.

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. 07. 26

Place of Issue: Anyang-si, Gyeonggi-do