

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 products

PRODUCT IDENTIFICATION			
Product Name	Model/Number	GMDN	Basic UDI Number
Charts, Eye, Visual Acuity	Digital Chart, HDC-9100N/PF	35922	88000196DC0018X
Intended use: The Huvitz Digital Chart (HDC-9100) is a computerized chart presenting device that provides charts for refractive correction test and various functional tests.			

meets 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 EN ISO13485:2016

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. 31