

## EC Declaration of Conformity

MANUFACTURER		
Name of Company	Address	Single Authorized Representative
Huvitz Co.,Ltd.	38, Burim-ro 170beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, 14055, Republic of Korea	Young-Hun, Kim

AUTHORIZED REPRESENTATIVE	
Name of Company	Address
Medical Device Safety Service GmbH	Schiffgraben 41, 30175 Hannover, Germany

We, the manufacturer, herewith declare that the products

PRODUCT IDENTIFICATION		
Product Name	Model	UMDNS Number
Tonometers, Ophthalmic	Non-Contact Tonometer HNT-1 Non-Contact Tonometer HNT-1P	16809

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

The medical device has been assigned to Class IIa 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 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
TÜ V Rheinland LGA Products GmbH Tillystraße 2, 90431, Nürnberg, Germany/0197	Start from 1NT00017D0001~and after

following the procedure relating to the EC Declaration of Conformity set out in Annex II 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: 

DATE: 2017.03.30