

## EC Declaration of Conformity

### MANUFACTURER

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

### AUTHORIZED REPRESENTATIVE

Name of Company	Address
Medical Device Safety Service GmbH	<b>Schiffgraben 41, 30175 Hannover, Germany</b>

We, the manufacturer, herewith declare that the products

### PRODUCT IDENTIFICATION

Product Name	Model	UMDNS Number
Tonometers, Ophthalmic	<b>Non-Contact Tonometer HNT-1 Non-Contact Tonometer HNT-1P</b>	<b>16809</b>

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

 0197

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
<b>TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431, Nürnberg, Germany/0197</b>	<b>Start from 1NT00017D0001~and after</b>

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