

# AUROLAB MASTER COPY

## DECLARATION OF CONFORMITY

### AUROLAB

No. 1, SIVAGANGAI MAIN ROAD, VEERAPANJAN  
MADURAI-625 020, TAMILNADU, INDIA  
TEL: +91-9489212354 / +91-7339571000  
Customer Care No: 18001037321  
E-MAIL- [info@aurolab.com](mailto:info@aurolab.com) / WEB: [www.aurolab.com](http://www.aurolab.com)

We declare that under our sole responsibility that

**Product** : Glaucoma Shunt

**Brand Name** : aadi

**UMDNS Code** : For Shunts- 13585

**GMDN Code** : For Glaucoma shunt – 61127

**MD Code** : 0203

**Model** : aadi-350

Lot No. from ..... to .....

Batch No: .....

For all lot numbers / serial numbers which are manufactured according to the specification of the Technical Documentation Issue 04 since 27/05/2020 and are documented in the general batch survey of **class II b according to Annex IX of Rule No. 8 in MDD 93/42/EEC** meets all the provisions of the directive 93/42/EEC which apply to it.

**Applied Standards**: Refer list of standards & guidelines in technical file TF-SN-01-GS, Issue 04 dated on 27/05/2020.

**Applied conformity assessment procedure**: Annex II without requirement of Annex II.4 of MDD 93/42/EEC

**Notified Body:**

TÜV Rheinland LGA Products GmbH  
Tillystrasse 2  
90431 Nuernberg  
Germany

**Notified body number**: 0197

**Reg No**: HD 2067790-1

**European representative:**

mdi Europa GmbH  
Langenhagener Straße 71  
D-30855 Langenhagen,  
Germany

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Quality Assurance Manager

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