

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

EasyMed Instruments Co., Ltd.

Mdi Europa GmbH

3/F, 5/F-6/F, Block A, Gupo Gongmao Building,
Fengxin Road, Fengxiang Industrial District,
Daliang, 528300 Shunde, Foshan, Guangdong,
China

Langenhagener Str. 71, 30855 Langenhagen,
Germany

We, the manufacturer, herewith declare that the product

QALM

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

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany

Registration No.: DD 60129671 0001

Effective date: 2018-08-16

Expiry date: 2023-04-09

following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

EasyMed Instruments Co., Ltd.

3/F, 5/F-6/F, Block A, Gupo Gongmao Building,
Fengxin Road, Fengxiang Industrial District,
Daliang, 528300 Shunde, Foshan, Guangdong, China

The product Qalm is manufactured exclusively for TensCare Ltd.

CHINA, 20 July 2020

Place, date

EC Declaration of Conformity
EMDOC_QALM, A0



Management Representative
Legally binding signature, Function