EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60116712 0001

Report No.: 17023744 008

Manufacturer:
Shenzhen Envisen Industry Co., Ltd.
2nd Floor, Block 1
40 Jianlong Street, Baoan Community
Henggang Town, Longgang District
Shenzhen
518115 Guangdong
China

Products:
Oximeter Probes, Temperature Probes, Breathing Circuits, Pulse Oximeters

Replaces Approval, Registration No.: HD 60104774 0001

Expiry Date: 2022-03-15

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2017-03-16

Date: 2017-03-09

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

S. Liu

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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