

Declaration of Conformity

Manufacturer: Xuzhou Yongkang Electronic Science Technology Co., Ltd
4F Building C8, 40 Jingshan Road, Economic and Technological
Development Zone, Xuzhou, China

European
Representative: Prolinx GmbH
Brehmstr.56 , 40239 Duesseldorf , GERMANY

Product Name: Multiparameter Patient Monitor
Models: YK-8000A, YK-8000B, YK-8000C, M8, E8, E10, E12, E15.

UMDNS Code: 33586

Classification (MDD, Annex IX): **IIb, Rule 10**
Conformity Assessment Route: **Annex II excluding (4)**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65,
80339 München, Germany

NB Identification number: 0123

(EC) Certificate(s): G1 17 09 92582 007

Expire date of the Certificate: 2021-06-29

Start of CE Marking: 2017-12-11

Place, Date of Issue: **Xuzhou, 2017-12-11**

Signature:

Name:

Position:


Zhao Xuecheng

General Manager