EC Certificate

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

Registration No.: HD 60135250 0001

Report No.: 17062731 004

Manufacturer:
Xiamen Linktop Technology Co., Ltd.
Room 501-2,502,503
North Building, Torch Hi-Tech Zone
No. 56-58, Huoju Road
Xiamen
361000 Fujian
China

Products:
Vital Signs Monitor

Additional site included:
No.29, Xiang Hong Road, Torch Hi-Tech Zone, XiangAn, Xiamen, China

Replaces Approval, Registration No.: HD 60126644 0001

Expiry Date: 2023-03-04

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: 2019-04-03

Date: 2019-04-03

Notified Body
TÜV Rheinland LGA Products GmbH
TÜVRheinland
III III
Zertifizierungsstelle
S. Liu

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.