ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 09 94339 003

Manufacturer:

HEBEI ZTEICT Software Technology Co., Ltd.
No.1 Shu-Gu Road
Economic & Technological Development Zone
066000 Qinhuangdao, Hebei
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

MEQUIPEX E.U.
Feldstrasse 39/1/3
4813 Altmuenster
AUSTRIA

Product Category(ies):

Homecare Multi-Parameter Recorder

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 7484049742

Valid from: 2016-11-03
Valid until: 2021-02-14

Date, 2016-11-03

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Facility(ies):

HEBEI ZTEICT Software Technology Co., Ltd.
No.1 Shu-Gu Road, Economic & Technological Development Zone, 066000 Qinhuangdao, Hebei, PEOPLE'S REPUBLIC OF CHINA

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