

Declaration of Conformity

Manufacturer	Shenzhen Hexin ZONDAN Medical Equipment Co., Ltd
Address	Floor 14,Block D,Dianlian Technology Building,the Crossing between South Circle Road and South Fuli Road,Guangming District,Shenzhen,China
European	Shanghai International Holding Corp. GmbH (Europe)
Representative	Eiffestrasse 80, 20537 Hamburg, GERMANY
Product	Pulse Oximeter
Model Code	A2\A3\A4\A5
GMDNS Code	17148

Classification

The medical device has been classified to class II b according to rule 10 of Annex IX of the Directive 93/42/EEC.

Conformity Assessment Route: Annex II without chapter 4 of the Directive 93/42/EEC on Medical Devices.

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

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices (MDD 93/42/EEC).

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

Identification number: CE0123

(EC) Certificate(s): G1171163196017

Expire date of the Certificate: 2023-04-10

Signature /Date: 2018.4.26

Name: Mr Lifeng

Position: GM

