

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 Representative Shanghai international Trading Corp .GmbH(Europe)
Product patient monitor
Model Code Apollo N1-A,Apollo N1-B, Apollo N2, Apollo N3, Apollo N4, Apollo N5, ZD120,ZD120D, ZD120E. IMD12, IMD8, A2, A3, A4, A5
GMDN Code 33586

Classification

The medical device has been assigned 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. 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: General Manager

