

Manufacturer:

Name: Hantech Medical Device Co., Ltd.

Add: No.288 Sanheng Road, Changhe Industrial Park, Cixi, Ningbo, China

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European Representative:

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Dimdi Code: DE/0000040627

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Product Name: Umbilical Cord Clamp (Sterile)

According to the size, it can be divided into one specification: 2001

Classification and relevant Rule of MDD: Class IS MDD 93/42/EEC Annex IX, Rule 1

Different models depend on the customer's specific requirements and no clinical manifestation difference.

The UMDNS code: 10876

Product Certification Conformity Assessment Route: Annex V of MDD 93/42/EEC

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All technical 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)

Standards applied:

list of (harmonized) standards (see part 10 of this technical file) for which documented evidence of compliance can be provided

Notified Body: TÜV SÜD Product Service GmbH • Zertifizierstelle • Ridlerstraße.65 • 80339 München • Germany

Identification Number: 0123

Certificate No.: Q5 002039 0002 Rev.04

Date CE mark was affixed: 2019-10-14

Signature of issue person:

Position: Management Representative

Date: April 19, 2021

Name:

Place: Ningbo

Valid until: 2024-02-07

