

Manufacturer:

Name: Hantech Medical Device Co., Ltd.

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

Zip Code: 315326

Tel: 0574-58995666-652

Fax: 0574-58995557

European Representative:

Name: Shanghai International Holding Corp. GmbH(Europe)

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Tel: +49-40-2513175

Fax: +49-40-255726

Dimdi Code: DE/0000040627

E-mail: shholding@hotmail.com

Product Name: Unsterilized Cord Clamp Clipper

According to the size, it can be divided into one specification: 3001

Classification and relevant Rule of MDR: Class I Medical Device REGULATION (EU) 2017/745 Annex
VIII, Rule 1Different models depend on the customer's specific requirements and no clinical manifestation
difference.

The UMDNS code: 15245

The UDI-DI: Not available

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 REGULATION (EU) 2017/745

Standards applied:

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

Signature of issue person:

Position: Management Representative

Date: April 19, 2021

Effective from: 2021-05-26

Name: Arnold Yang

Place: Ningbo

