宁波汉科医疗器械有限公司 / Hantech Medical Device Co., Ltd.

Declaration of Conformity
符合性声明

文件编号 / Document No: CE-FP-E-03	版本号/ Revision No: B
编制 / Written By: 胡科明	日期 / Date: 2019.4.11
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版本号 Revision No.	修改日期 Revision Date	描述 Description	编制 Revised By
A	2018.11	首次发布	周挺挺
B	2019.04	修改证书有效期	胡科明

Manufacturer:

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Product Name：Amniotic Membrane Perforator
According to the size, it can be divided into five specifications: 265mm(SF-EA-0010)
Classification and relevant Rule of MDD：Ⅱa MDD 93/42/EEC Annex IX, Rule 6
Different models depend on the customer's specific requirements and no clinical manifestation difference.

The UMDNS code：12990

Product Certification Conformity Assessment Route: Annex V.3 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 prmises 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 • Ridlerstraβe.65 • 80339 München • Germany
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CE Certificate No.：G2 002039 004 Rev.00 Valid until：2024-03-25
Date CE mark was affixed：2019-03-26

Signature of issue person:
Position: General Manager
Date: 2019-04-11

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