DECLARATION OF CONFORMITY

Manufacturer:

Name: Jiangsu Embrace Science&Technology Development Co., Ltd.

Add: 29-2 Yingbin Road, Huai'an Economic and Technological Development Zone, Huai'an, Jiangsu

Zip Code: 223001

Tel: +86 0517-85969155

European Representative:

Name: Riomavix S.L.

Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain

Tel.: +34 658 396 230

E-mail: riomavix@gmail.com

Product Name: Pre-filled flush syringe

Specification: Pre-filled flush syringe with 0.9% sodium chloride solution. See the Appendix A

Classification and relevant Rule of MDD： IIa Rule 2

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

15256 (UMDNS Code)

Product Certification Conformity Assessment Route: Directive 93/42/EEC Annex II.3

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.

Jiangsu Embrace Science&Technology Development Co., Ltd. is exclusively responsible for the declaration of conformity.

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
Identification Number: 0123
CE Certificate No.: G2102433 0001 Rev.00 Valid until: 2024-05-26
Date CE mark was affixed: 2019-11-26

Product List

S/N	REF	Model/ specification
1	catheflush3ml	Pre-filled flush syringe 3ml
2	catheflush5ml	Pre-filled flush syringe 5ml
3	catheflush10ml	Pre-filled flush syringe 10ml

Signature:

Position: Quality Director

Name: Jiang Huaili

Date: 2024-02-21

Place: Huai'an