EC Declaration of Conformity

Manufacturer

Name: Ningbo HLS Medical Products Co., Ltd
Address: No.3918-3928, Zhouxi Road, Zhouxiang Town,315324, Cixi City, Zhejiang,
PEOPLE'S REPUBLIC OF CHINA

EC- Representative

Name:MedPath GmbH
Address: Mies- van- der- Rohe-Strasse8,80807 Munich, Germany

Products

Products	Specifications	Classification Rules	Classification
Long Scissors	M50321	Rule 5 of Annex IX,MDD 93/42/EEC	I sterile
Pozzi forceps	M50322	Rule 5 of Annex IX,MDD 93/42/EEC	I sterile
Pozzi forceps	M50322-4F	Rule 5 of Annex IX,MDD 93/42/EEC	I sterile
Cheron forceps	M50323	Rule 5 of Annex IX,MDD 93/42/EEC	I sterile
Cheron forceps	M50323-4F	Rule 5 of Annex IX,MDD 93/42/EEC	I sterile
Intrauterine contraceptive device placement	M50330	Rule 5 of Annex IX,MDD 93/42/EEC	I sterile
Exocervical/endocervical brushes	M50401	Rule 5 of Annex IX,MDD 93/42/EEC	I sterile
Endocervical brushes	M50411	Rule 5 of Annex IX,MDD 93/42/EEC	I sterile
Ayres Spatula	M50422	Rule 5 of Annex IX,MDD 93/42/EEC	I sterile
Hysterometer 10 mm	M50430	Rule 5 of Annex IX,MDD 93/42/EEC	I sterile
Hysterometer 12 mm	M50431	Rule 5 of Annex IX,MDD 93/42/EEC	I sterile
Hysterometer 14 mm	M50432	Rule 5 of Annex IX,MDD 93/42/EEC	I sterile
Endocyte	M50440	Rule 5 of Annex IX,MDD 93/42/EEC	I sterile
Sampling brush	M50450	Rule 5 of Annex IX,MDD 93/42/EEC	I sterile

Statement

We, the manufacturer, herewith declare in our own responsibility that the above- mentioned products meet the provisions of the Council Directive 93/42/EEC of 14th June 1993 concerning medical devices, amended by Council Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

Applicable Harmonized Standards

EN ISO 14971:2012

Conformity Assessment Procedures

Production quality assurance system of Council directive 93/42/EEC on Medical Devices (MDD). Annex VII+AnnexV(DevicesClass I sterile)

Notified Body

Name. TOV SOD Product Service GmbH
Identification No.:0123
Address: Zertifizierstelle, Ridlerstraße 65,80339 München,GERMANY

Certificate information

CE Certificate No.: G2S 086249 0005 Rev.01

CE Certificate valid until: 2024.01.19

Signature of issue person:

Name: Beijiang Wu

Position. General Manager

Date: 2024.10.15

Place: Ningbo, China