SHANCHUAN GROUP
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ZiBo Qray International Co., Ltd.
JiangXi YiKang Medical Instrument Group Co., Ltd.
ShanDong ZiBo ShanChuan Medical Instruments Co., Ltd.
Tel: 008618560896869 Fax:00865332222678
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Declaration of Conformity

Manufacturer Name: Zibo Qray International Co., Ltd.
Add: No.77 Zhanghuan Road, 255000, Zibo City, Shandong, People’ s Republic of China
European Representative
Name: ZOUSTECH S.L.
Address: PSO. CASTELLANA,141-PLANTA 19,28046 MADRID,SPAIN
Product Name: Sterile Vaginal Dilators for Single Use
Classification and relevant Rule: I sterile according to MDD Annex IX, Rule 5
UMDNS code: 11267
CE conformity assessment route: Annex V.3

REF (Product ID Number)	Specification and Size (product variable)	REF (Product ID Number)	Specification and Size (product variable)
QR10-0101	WITH LATERAL SCREW, S SIZE	QR10-0301	WITH PULL-PUSH, S SIZE
QR10-0102	WITH LATERAL SCREW, M SIZE	QR10-0302	WITH PULL-PUSH, M SIZE
QR10-0103	WITH LATERAL SCREW, L SIZE	QR10-0303	WITH PULL-PUSH, L SIZE
QR10-0201	WITH HOOK, S SIZE	QR10-0401	WITH MIDDLE SCREW, S SIZE
QR10-0202	WITH HOOK, M SIZE	QR10-0402	WITH MIDDLE SCREW, M SIZE
QR10-0203	WITH HOOK, L SIZE	QR10-0403	WITH MIDDLE SCREW, L SIZE

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 promise of the manufacturer. Our company is exclusively responsible for this Declaration of Conformity.

DIRECTIVES

General applicable directives:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES (MDD 93/42/EEC)

Notified Body: TÜV SÜD Product Service GmbH, Ridlestrasse. 65, 80339 Münich, Germany
Identification Number: 0123
CE Certificate No.: G2S 003509 0003 Rev.01
CE Certificate valid until: 2023-04-23
Date CE mark was affixed: 2019-08-02

Digitally signed by Bolea Petru
Date: 2022.09.14 07:14:46 EEST
Reason: MoldSign Signature
Location: Moldova

Signature of issue person:
Name: Rachel Li
Position: General Manager
Place: Zibo, China

for and on behalf of ZIBO QRAY INTERNATIONAL CO., LTD
Authorized signature(s)