



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 Munich, Germany

Identification Number: 0123

CE Certificate No.: G2S 003509 0003 Rev.01

CE Certificate valid until: 2023-04-23

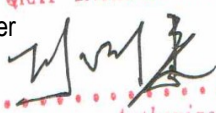
Date CE mark was affixed: 2019-08-02

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)