EC Declaration of Conformity

Doc No : DC-038
Rev.No : 7

Manufacturer :
DiaDent Group International
16, Osongsaengmyeong 4-ro Osong-eup Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do,
28161, Republic of Korea

Authorized Representative :
DiaDent Europe B.V.
Antennestraat 70, 1322AS Almere, the Netherlands

We, the manufacturer, herewith declare that the products

DIAFLEX Syringes

(Type III, V)

GMDN : 35970

meet the provisions of The Medical Devices Directive 93/42/EEC amended by 2007/47/EC which apply to them.

The medical device has been assigned to ClassI(Rule 5) according to Annex IX of the Medical Devices Directive 93/42/EEC amended by 2007/47/EC.

The product concerned has been designed and manufactured under a quality management system according to Annex VII of the Medical Devices Directive 93/42/EEC amended by 2007/47/EC.

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of the Medical Devices Directive 93/42/EEC amended by 2007/47/EC

The above mentioned declaration of conformity is exclusively under the responsibility of

DiaDent Group International
16, Osongsaengmyeong 4-ro Osong-eup Heungdeok-gu, Cheongju-si Chungcheongbuk-do, 28161, Republic of Korea

2020-06-01
Date

Signature

DiaDent®
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