

EC Declaration of Conformity

Doc No : DC-110(R)
Rev.No : 04

Manufacturer :
DiaDent Group International
16, Osongsaengmyeong 4-ro Osong-eup Heungdeok-gu,
We, the manufacturer, herewith declare that the products

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

DIAFIL FLOW

(Attachment 1. Model list)

GMDN : 35870

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 Class IIa(Rule 8) according to Annex IX of the Medical Devices Directive 93/42/EEC amended by 2007/47/EC. It bears the mark



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

Compliance of the designated product with The Medical Devices Directive 93/42/EEC amended by 2007/47/EC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No : HD 60149568 0001(DIADE_CL607_2024-05-14)
Issue date : 2024-05-14
Expiry date : 2028-12-31

following the procedure relating to the EC Declaration of Conformity set out in Annex II 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

2025-11-05

Date

KabSun Lee
/ PRRC of DiaDent Group International

Attachment 1. Model list

DoC No. : DC-110(R)_Rev.04

Product name or Trade Name	Model Name
DIAFIL FLOW	DIAFIL FLOW A1 Economic Package
	DIAFIL FLOW A2 Economic Package
	DIAFIL FLOW A3 Economic Package
	DIAFIL FLOW A3.5 Economic Package
	DIAFIL FLOW A2O Economic Package
	DIAFIL FLOW A3O Economic Package
	DIAFIL FLOW B2 Economic Package
	DIAFIL FLOW B3 Economic Package
	DIAFIL FLOW C2 Economic Package
	DIAFIL FLOW A1 Refill Package
	DIAFIL FLOW A2 Refill Package
	DIAFIL FLOW A3 Refill Package
	DIAFIL FLOW A3.5 Refill Package
	DIAFIL FLOW A2O Refill Package
	DIAFIL FLOW A3O Refill Package
	DIAFIL FLOW B2 Refill Package
	DIAFIL FLOW B3 Refill Package
	DIAFIL FLOW C2 Refill Package
	DIAFIL FLOW A1 Intro Kit
	DIAFIL FLOW A2 Intro Kit
	DIAFIL FLOW A3 Intro Kit
	DIAFIL FLOW A3.5 Intro Kit
	DIAFIL FLOW A2O Intro Kit
	DIAFIL FLOW A3O Intro Kit
	DIAFIL FLOW B2 Intro Kit
	DIAFIL FLOW B3 Intro Kit
DIAFIL FLOW C2 Intro Kit	
eco Flow	eco Flow A1 Refill Package
	eco Flow A2 Refill Package
	eco Flow A3 Refill Package
	eco Flow A3.5 Refill Package
	eco Flow A2O Refill Package
	eco Flow A3O Refill Package
	eco Flow B2 Refill Package
	eco Flow B3 Refill Package
eco Flow C2 Refill Package	