SIMPLIVIA

EC DECLERATION OF CONFORMITY

According to Annex V of the council directive 93/42/EEC, 2007/47 EC

Amendment concerning medical device

We: Simplivia Healthcare Ltd., P.O.Box 888, KIRYAT SHMONA 1101801
(PHON E: 972-4-6908800; FAX: 972-9-8921665)

Declare under our sole responsibility that the products:

Chemfort *TM*

Closed Drug Reconstitution System

Meet the provisions of the Council Directive (MDD) 93/42/EEC, 2007/47/EC amendment concerning medical devices which apply to them:
The product is intended to be used for reconstituting and administration of drugs including cytotoxic drugs and prepare items for delivery by I.V. Infusion therefore is in Class I Sterile, according to rule#2 and Annex V of lite Medical Device Directive.

Conformity assessment was performed according to Annex V and Annex VII.
Signature established within the EU who has been empowered to enter in to commitments on our behalf:

Authorized Representative:
Donawa LiveScience Consulting Srl,
Piazza Albania, 10 - 00153 Rome, Italy
TEL: + 39 06 578 2665, FAX: + 39 06 574 3786
info@donawa.com

Notified Body:
MDC - Medical Device Certification Gmbh - 0483
Kriegerstrase 6 - D-70191 Stuttgart, Germany
TEL: + 49 (0)711 253597-0
mdc@mdc-ce.de

Date: 16 March 2020 ***Name***: Shay Shaham VP QA/RA ***Signature***: Shay Shaham

Simplivia healthcare Ltd., Kiryat Shmona, 1101801, Israel

The Chemfort™ Closed Drug Reconstitution System under this EC Declaration of Conformity includes the following components:

MG245248	Chemfort *20 mm Vial Adaptor and 13 mm convertor*
MG245266	Chemfort *28mm Vial Adaptor*
MG245269	Chemfort 32mm Vial Adaptor
MG245267	Chemfort Syringe Adaptor
MG245277	Chemfort Syringe Adaptor Lock
MG245250	Chemfort *Luer Lock Adaptor*
MG245251	Chemfort Bag Adaptor SP
MG245249	Chemfort Bag Adaptor LL
MG245746	Chemfort *Bag Adaptor LL (with Female Luer)*
MG245279	Chemfort Bag Adaptor LL PVC Free
MG245636	Chemfort IV Safety Set
MG245635	Chemfort *IV Safety Set (with 0.2 Micron. Filter)*
MG245686	Chemfort IV Safety Set PVC Free

Date: 16 March 2020 ***Name***: Shay Shaham VP QA/RA ***Signature***: Shay Shaham

Simplivia healthcare Ltd., Kiryat Shmona, 1101801, Israel

The Doc is valid until: May 26, 2024

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