EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

Simplivia Healthcare Ltd.
North Industrial Zone, P.O. Box 888
Kiryat Shmona, 1101801
Israel

for the scope

Tevadaptor, Chemfort and CADM (closed drug reconstitution system, closed system transfer device), Infusion Sets

has introduced and applies a

Quality System

for the aspects of manufacture concerned with securing and maintaining sterile conditions as specified in Annex V, Section 3.

The mdc audit has proven that this quality system meets all requirements according to

Annex V – Section 3
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex V, Section 4.

Valid from	2021-05-18
Valid until	2024-05-26
Registration no.	D1459800003
Report no.	P20-01876-191195
Stuttgart	2021-05-18

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
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