

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

Notified Body Confirmation Letter

Registration no.: D1459800007

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that mdc medical device certification GmbH (Kriegerstr. 6, 70191 Stuttgart, Germany), a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0483 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

**Simplivia Healthcare Ltd.
North Industrial Zone, P.O. Box 888
Kiryat Shmona, 1101801
Israel
SRN: IL-MF-000035592**

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which a MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which a MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by 20 March 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by Regulation (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Stuttgart, 2024-05-22



Head of Notified Body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
MG245148 Chemfort 20mm Vial Adaptor SL and 13mm Convertor	Class I devices placed on the market in sterile condition	N/A	D1459800003, mdc medical device certification GmbH 0483
MG245181 Chemfort Bag Adaptor SPT PVC FREE	Class I devices placed on the market in sterile condition	MG245581 SIMPLIVIA Spike Port Adaptor PVC Free	D1459800003, D1459800005 mdc medical device certification GmbH 0483
MG245248 Chemfort 20 mm Vial Adaptor and 13 mm convertor	Class I devices placed on the market in sterile condition	N/A	D1459800003, mdc medical device certification GmbH 0483
MG245249 Chemfort Bag Adaptor LL	Class I devices placed on the market in sterile condition	N/A	D1459800003, mdc medical device certification GmbH 0483
MG245250 Chemfort Luer Lock Adaptor	Class I devices placed on the market in sterile condition	N/A	D1459800003, mdc medical device certification GmbH 0483
MG245251 Chemfort Bag Adaptor SP	Class I devices placed on the market in sterile condition	N/A	D1459800003, mdc medical device certification GmbH 0483
MG245252 Bag Adaptor Chemfort Port	Class I devices placed on the market in sterile condition	N/A	D1459800003, mdc medical device certification GmbH 0483
MG245253 Closed Y Inline Set	Class I devices placed on the market in sterile condition	N/A	D1459800003, mdc medical device certification GmbH 0483
MG245254 Closed Adaptor Spike Port	Class I devices placed on the market in sterile condition	N/A	D1459800003, mdc medical device certification GmbH 0483
MG245255 Closed Secondary IV Set	Class I devices placed on the market in sterile condition	N/A	D1459800003, mdc medical device certification GmbH 0483
MG245266 Chemfort 28mm Vial Adaptor	Class I devices placed on the market in sterile condition	N/A	D1459800003, mdc medical device certification GmbH 0483
MG245267 Chemfort Syringe Adaptor	Class I devices placed on the market in sterile condition	N/A	D1459800003, mdc medical device certification GmbH 0483
MG245268 Chemfort Sterile Caps for Syringe Adaptor	Class I devices placed on the market in sterile condition	N/A	D1459800003, mdc medical device certification GmbH 0483
MG245269 Chemfort 32mm Vial Adaptor	Class I devices placed on the market in sterile condition	N/A	D1459800003, mdc medical device certification GmbH 0483
MG245277 Chemfort Syringe Adaptor Lock	Class I devices placed on the market in sterile condition	N/A	D1459800003, mdc medical device certification GmbH 0483
MG245279 Chemfort Bag Adaptor LL PVC Free	Class I devices placed on the market in sterile condition	N/A	D1459800003, mdc medical device certification GmbH 0483
MG245591 Chemfort Catheter Adaptor	Class I devices placed on the market in sterile condition	MG245590 SIMPLIVIA Catheter Adaptor	D1459800003, D1459800005 mdc medical device certification GmbH 0483
MG245635 Chemfort IV Safety Set (with 0.2 Micron. Filter)	Class I devices placed on the market in sterile condition	N/A	D1459800003, mdc medical device certification GmbH 0483
MG245636 Chemfort IV Safety Set	Class I devices placed on the market in sterile condition	N/A	D1459800003, mdc medical device certification GmbH 0483

MG245686 Chemfort IV Safety Set PVC Free	Class I devices placed on the market in sterile condition	N/A	D1459800003, mdc medical device certification GmbH 0483
MG245700 Chemfort Syringe Adaptor Lock II	Class I devices placed on the market in sterile condition	N/A	D1459800003, mdc medical device certification GmbH 0483
MG245746 Chemfort Bag Adaptor (SPT)	Class I devices placed on the market in sterile condition	MG245551 SIMPLIVIA Spike Port Adaptor	D1459800003, D1459800005 mdc medical device certification GmbH 0483

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
MG245538 IV Giving Set for Paclitaxel	Class I (sterile)	N/A	D1459800003, mdc medical device certification GmbH 0483
MG245544 SIMPLIVIA TREE Inline Set 4 FLC	Class I (sterile)	N/A	D1459800003, mdc medical device certification GmbH 0483

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-05-22	D1459800007	Initial