FRESENIUS KABI

EU Declaration of Conformity with article list

FRESENIUS KABI

EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Medical Device Regulation (EU) 2017/745 according to EC-certificate No. G10 037258 0012 Rev.00 and expiration date 09 March 2026, Issued by Notified Body TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123

VIGILANT SOFTWARE SUITE
Accessory of infusion system

Product name
Refer to attachment

Article number
Refer to attachment

From serial number / Batch number
Vigilant Software Suite (in Key2): Not applicable (Software has not a physical support)

Device classification according to Annex VIII,
Clause 6.4, Rule 12: Class IIb

Common Specifications used and in relation to which conformity is declared: N/A

We

Fresenius Kabi AG
Else-Kröner-Str.1
61352 Bad Homburg, GERMANY
Single Registration Number (SRN): DE-MF-000009273

manufacturer of the above product, hereby declare under our sole responsibility for this Declaration of Conformity that the referenced products comply with all relevant provisions of the Medical Device Regulation 2017/745 and any other relevant Union legislation that provides for the issuing of this EU Declaration of Conformity. The products comply with the general safety and performance requirements of Annex I, further applicable standards and/or other normative documents as listed in the applicable technical documentation. All supporting documentation is kept under the premises of the manufacturer.

Place and date of issue/	Name (printed letters), position and signature of authorized person/
Brezins, on 22 July 2021	Laurent KELLER Regulatory Affairs Manager

Valid starting with the original date of the document until product change

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Attachment to EU DECLARATION OF CONFORMITY

ACCESSORY OF INFUSION SYSTEM

Article number	Product name	Basic UDI-DI
ZK288001	Vigilant Software Suite (in Key2)	4052682AND21012bSD000039