
EU Declaration of Conformity with article list



EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to
EC-certificate No. G10 037258 0012 Rev. 02 and Expiration Date March 09th, 2026
issued by Notified Body TÜV Süd Product Service GmbH,
Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123

Product Family Description
Syringe Infusion Pump

Product name
Refer to attachment

Article number
Refer to attachment

From serial number / Batch number
Refer to attachment

Device classification according to Annex VIII
AGILIA SP PCA WIFI: Rule 12, Class IIb

We

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

manufacturer of the above products, 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/

Brezins, on 23 July, 2024

Name (printed letters), position and signature of authorized person/

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

SYRINGE INFUSION PUMP

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z020101*	Agilia SP PCA WIFI	25869613	4052682AIV01012bCF000ACG
Z020110*	Agilia SP PCA WIFI FR	26047305->26047307	
Z020112*	Agilia SP PCA WIFI NOA	Not yet manufactured	
Z020120	Agilia SP PCA WIFI DE	Not yet manufactured	
Z020130*	Agilia SP PCA WIFI GB	Not yet manufactured	
Z020131*	Agilia SP PCA WIFI MEA	26047394->26047395	
Z020142	Agilia SP PCA WIFI AR	Not yet manufactured	
Z020147*	Agilia SP PCA WIFI TR	Not yet manufactured	
Z020179*	Agilia SP PCA WIFI ID	Not yet manufactured	
Z020189*	Agilia SP PCA WIFI ISE	Not yet manufactured	
Z020192	Agilia SP PCA WIFI AU	Not yet manufactured	

** Device with embedded software version 4.2 and either TI (E03 as Wi-Fi software version) or Plexus (D62 as Wi-Fi software version) Wi-Fi module.*