
Template for 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

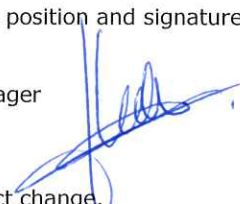
manufacturer of the above products, hereby declare under our sole responsibility for this Declaration of Conformity that the referenced products comply with all relevant provisions of the Medical Device Regulation 2017/745 and any other relevant Union legislation that provides for the issuing of this 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/

Brézins, on April 07, 2025

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****AGILIA SP PCA WIFI**

Article Number	Product Name	Basic UDI-DI	Intended Purpose	Serial Number/Batch Number
Z020101**	Agilia SP PCA WIFI	4052682AIV01012bCF000ACG	Infusion Pumps and Accessories for Administration of Fluids	25869613
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
Z020132*	Agilia SP PCA WIFI MX			Not yet manufactured
Z020136*	Agilia SP PCA WIFI TH			Not yet manufactured
Z020139*	Agilia SP PCA WIFI VN			Not yet manufactured
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
Z020197*	Agilia SP PCA WIFI IN			Not yet manufactured

Note: Device without "" is device with embedded software versions 3.3 or 4.1.*

** 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.*

*** Device with embedded software version 4.3 and either TI (E03 as Wi-Fi software version) or Plexus (D62 as Wi-Fi software version) Wi-Fi module.*