

EU DECLARATION OF CONFORMITY

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Product Family Description

Syringe Infusion Pump

Product name
Refer to attachment

Article number
Refer to attachment

From Serial number / Batch number AGILIA SP PCA WIFI: 25869613

We

Fresenius Kabi AG, Else-Kröner-Str. 1, 61352 Bad Homburg, Germany

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 Directive 2011/65/EU and its transposition into national laws.

Place and date of issue

Name (printed letters), position and signature

Brezins, Dec. 20, 2024

Laurent KELLER Regulatory Affairs Manager

Valid starting with the above date until product change

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FKBZ-D040509-1



Attachment to EU DECLARATION OF CONFORMITY

SYRINGE INFUSION PUMP

AGILIA SP PCA WIFI

Article number	Product name
Z020101**	Agilia SP PCA WIFI
Z020110*	Agilia SP PCA WIFI FR
Z020112*	Agilia SP PCA WIFI NOA
Z020120	Agilia SP PCA WIFI DE
Z020130*	Agilia SP PCA WIFI GB
Z020131*	Agilia SP PCA WIFI MEA
Z020142	Agilia SP PCA WIFI AR
Z020147*	Agilia SP PCA WIFI TR
Z020179*	Agilia SP PCA WIFI ID
Z020189*	Agilia SP PCA WIFI ISE
Z020192	Agilia SP PCA WIFI AU

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

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^{*} 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).