

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, April 97, 2021

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 |
| Z020132* | Agilia SP PCA WIFI MX |
| Z020136* | Agilia SP PCA WIFI TH |
| Z020139* | Agilia SP PCA WIFI VN |
| 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 |
| Z020197* | Agilia SP PCA WIFI IN |

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).