
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 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 range: 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 March 31, 2022

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

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z018510	AGILIA SP FR	25149979	4052682AIV01012bCF000ACG
Z018512	AGILIA SP NOA	Not yet manufactured	
Z018520	AGILIA SP DE	24964865	
Z018531	AGILIA SP MEA	25057056	
Z018536	AGILIA SP TH	Not yet manufactured	
Z018537	AGILIA SP MY	Not yet manufactured	
Z018543	AGILIA SP PT	Not yet manufactured	
Z018550	AGILIA SP SE	25149979	
Z018560	AGILIA SP IT	25149979	
Z018570	AGILIA SP NL	25149979	
Z018580	AGILIA SP ES	24997561	
Z018589	AGILIA SP ISE	25170079	
Z018591	AGILIA SP ZA	25170039	
Z018592	AGILIA SP AU	From 24964895 to 24964924	
Z018597	AGILIA SP IN	Not yet manufactured	

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AGILIA SP MC

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z018610	AGILIA SP MC FR	25149979	4052682AIV01012bCF000ACG
Z018612	AGILIA SP MC NOA	Not yet manufactured	
Z018620	AGILIA SP MC DE	24964865	
Z018631	AGILIA SP MC MEA	25057056	
Z018636	AGILIA SP MC TH	Not yet manufactured	
Z018637	AGILIA SP MC MY	Not yet manufactured	
Z018641	AGILIA SP MC CO	Not yet manufactured	
Z018643	AGILIA SP MC PT	Not yet manufactured	
Z018650	AGILIA SP MC SE	25149979	
Z018651	AGILIA SP MC FI	24997561	
Z018657	AGILIA SP MC DK	25149979	
Z018660	AGILIA SP MC IT	25149979	
Z018670	AGILIA SP MC NL	25149979	
Z018680	AGILIA SP MC ES	24997561	
Z018681	AGILIA SP MC CL	25170039	
Z018689	AGILIA SP MC ISE	25170079	
Z018691	AGILIA SP MC ZA	25170039	
Z018692	AGILIA SP MC AU	From 24964895 to 24964924	
Z018697	AGILIA SP MC IN	Not yet manufactured	

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AGILIA SP MC WIFI

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z018710	AGILIA SP MC WIFI FR	25149979	4052682AIV01012bCF000ACG
Z018712	AGILIA SP MC WIFI NOA	Not yet manufactured	
Z018720	AGILIA SP MC WIFI DE	24964865	
Z018730	AGILIA SP MC WIFI GB	From 24845937 to 24845966 And From 24997083	
Z018731	AGILIA SP MC WIFI MEA	25057056	
Z018736	AGILIA SP MC WIFI TH	Not yet manufactured	
Z018737	AGILIA SP MC WIFI MY	Not yet manufactured	
Z018738	AGILIA SP MC WIFI SG	Not yet manufactured	
Z018741	AGILIA SP MC WIFI CO	Not yet manufactured	
Z018750	AGILIA SP MC WIFI SE	25149979	
Z018751	AGILIA SP MC WIFI FI	24997561	
Z018757	AGILIA SP MC WIFI DK	25149979	
Z018760	AGILIA SP MC WIFI IT	25149979	
Z018770	AGILIA SP MC WIFI NL	25149979	
Z018789	AGILIA SP MC WIFI ISE	25170079	
Z018791	AGILIA SP MC WIFI ZA	25170039	
Z018792	AGILIA SP MC WIFI AU	From 24964895 to 24964924	
Z018797	AGILIA SP MC WIFI IN	Not yet manufactured	

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AGILIA SP TIVA

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z018810	AGILIA SP TIVA FR	25149979	4052682AIV01012bCF000ACG
Z018812	AGILIA SP TIVA NOA	Not yet manufactured	
Z018820	AGILIA SP TIVA DE	24964865	
Z018830	AGILIA SP TIVA GB	From 24845937 to 24845966 And From 24997083	
Z018831	AGILIA SP TIVA MEA	25057056	
Z018843	AGILIA SP TIVA PT	Not yet manufactured	
Z018850	AGILIA SP TIVA SE	25149979	
Z018851	AGILIA SP TIVA FI	24997561	
Z018857	AGILIA SP TIVA DK	25149979	
Z018860	AGILIA SP TIVA IT	25149979	
Z018870	AGILIA SP TIVA NL	25149979	
Z018881	AGILIA SP TIVA CL	25170039	
Z018889	AGILIA SP TIVA ISE	25170079	
Z018891	AGILIA SP TIVA ZA	25170039	
Z018892	AGILIA SP TIVA AU	From 24964895 to 24964924	
Z018897	AGILIA SP TIVA IN	Not yet manufactured	

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AGILIA SP TIVA WIFI

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z018910	AGILIA SP TIVA WIFI FR	25149979	4052682AIV01012bCF000ACG
Z018920	AGILIA SP TIVA WIFI DE	24964865	
Z018930	AGILIA SP TIVA WIFI GB	From 24845937 to 24845966 And From 24997083	
Z018931	AGILIA SP TIVA WIFI MEA	25057056	
Z018950	AGILIA SP TIVA WIFI SE	25149979	
Z018951	AGILIA SP TIVA WIFI FI	24997561	
Z018957	AGILIA SP TIVA WIFI DK	25149979	
Z018960	AGILIA SP TIVA WIFI IT	25149979	
Z018970	AGILIA SP TIVA WIFI NL	25149979	
Z018989	AGILIA SP TIVA WIFI ISE	25170079	
Z018991	AGILIA SP TIVA WIFI ZA	25170039	
Z018992	AGILIA SP TIVA WIFI AU	From 24964895 to 24964924	
Z018997	AGILIA SP TIVA WIFI IN	Not yet manufactured	