
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 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 *May 02, 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

AGILIA SP

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z018500	AGILIA SP	24963951	4052682AIV01012bCF000ACG
Z018501*	AGILIA SP	25890667	
Z018510	AGILIA SP FR	25149979	
Z018512	AGILIA SP NOA	25294956	
Z018520	AGILIA SP DE	24964865	
Z018531	AGILIA SP MEA	25057056	
Z018532	AGILIA SP MX	Not yet manufactured	
Z018536	AGILIA SP TH	Not yet manufactured	
Z018537	AGILIA SP MY	Not yet manufactured	
Z018539	AGILIA SP VN	Not yet manufactured	
Z018540	AGILIA SP BR	25264353	
Z018542	AGILIA SP AR	25472009	
Z018543	AGILIA SP PT	25239813	
Z018544	AGILIA SP SK	25449952	
Z018547	AGILIA SP TR	25449952	
Z018548	AGILIA SP RO	25359480	
Z018549	AGILIA SP BG	25359480	
Z018550	AGILIA SP SE	25149979	
Z018552	AGILIA SP SI	Not yet manufactured	
Z018553	AGILIA SP HR	25447870	
Z018560	AGILIA SP IT	25149979	
Z018562	AGILIA SP GR	25359480	
Z018564	AGILIA SP CY	25359480	
Z018570	AGILIA SP NL	25149979	
Z018579	AGILIA SP ID	Not yet manufactured	
Z018580	AGILIA SP ES	24997561	
Z018583	AGILIA SP UY	Not yet manufactured	
Z018589	AGILIA SP ISE	25170079	

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Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z018591	AGILIA SP ZA	25170039	
Z018592	AGILIA SP AU	From 24964895 to 24964924 And From 25380601	
Z018593	AGILIA SP PL	25381696	
Z018594	AGILIA SP TW	Not yet manufactured	
Z018595	AGILIA SP KR	Not yet manufactured	
Z018597	AGILIA SP IN	25264293	

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AGILIA SP MC

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z018600	AGILIA SP MC	24963951	4052682AIV01012bCF000ACG
Z018601*	AGILIA SP MC	25868794	
Z018610	AGILIA SP MC FR	25149979	
Z018612	AGILIA SP MC NOA	25294956	
Z018620	AGILIA SP MC DE	24964865	
Z018631	AGILIA SP MC MEA	25057056	
Z018632	AGILIA SP MC MX	Not yet manufactured	
Z018636	AGILIA SP MC TH	Not yet manufactured	
Z018637	AGILIA SP MC MY	Not yet manufactured	
Z018639	AGILIA SP MC VN	Not yet manufactured	
Z018640	AGILIA SP MC BR	25264353	
Z018641	AGILIA SP MC CO	25294956	
Z018642	AGILIA SP MC AR	25472009	
Z018643	AGILIA SP MC PT	25239813	
Z018644	AGILIA SP MC SK	25449952	
Z018645	AGILIA SP MC HU	25359480	
Z018646	AGILIA SP MC CZ	25449436	
Z018647	AGILIA SP MC TR	25449952	
Z018648	AGILIA SP MC RO	25359480	
Z018649	AGILIA SP MC BG	25359480	
Z018650	AGILIA SP MC SE	25149979	
Z018651	AGILIA SP MC FI	24997561	
Z018652	AGILIA SP MC SI	Not yet manufactured	
Z018653	AGILIA SP MC HR	25447870	
Z018655	AGILIA SP MC NO	Not yet manufactured	
Z018657	AGILIA SP MC DK	25149979	
Z018660	AGILIA SP MC IT	25149979	
Z018662	AGILIA SP MC GR	25359480	
Z018664	AGILIA SP MC CY	25359480	
Z018670	AGILIA SP MC NL	25149979	
Z018679	AGILIA SP MC ID	Not yet manufactured	
Z018680	AGILIA SP MC ES	24997561	
Z018681	AGILIA SP MC CL	25170039	
Z018683	AGILIA SP MC UY	Not yet manufactured	

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Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z018689	AGILIA SP MC ISE	25170079	
Z018691	AGILIA SP MC ZA	25170039	
Z018692	AGILIA SP MC AU	From 24964895 to 24964924 And From 25380601	
Z018693	AGILIA SP MC PL	25381696	
Z018694	AGILIA SP MC TW	Not yet manufactured	
Z018695	AGILIA SP MC KR	Not yet manufactured	
Z018697	AGILIA SP MC IN	25264293	

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AGILIA SP MC WIFI

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z018700	AGILIA SP MC WIFI	25449951	4052682AIV01012bCF000ACG
Z018701*	AGILIA SP MC WIFI	25868764	
Z018710	AGILIA SP MC WIFI FR	25149979	
Z018712	AGILIA SP MC WIFI NOA	25294956	
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	
Z018732	AGILIA SP MC WIFI MX	Not yet manufactured	
Z018733	AGILIA SP MC WIFI PH	25449952	
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	
Z018739	AGILIA SP MC WIFI ID	Not yet manufactured	
Z018740	AGILIA SP MC WIFI BR	25264353	
Z018741	AGILIA SP MC WIFI CO	25294956	
Z018742	AGILIA SP MC WIFI AR	25472009	
Z018744	AGILIA SP MC WIFI SK	25449952	
Z018745	AGILIA SP MC WIFI HU	25359480	
Z018746	AGILIA SP MC WIFI CZ	25449436	
Z018748	AGILIA SP MC WIFI RO	25359480	
Z018750	AGILIA SP MC WIFI SE	25149979	
Z018751	AGILIA SP MC WIFI FI	24997561	
Z018752	AGILIA SP MC WIFI SI	Not yet manufactured	
Z018755	AGILIA SP MC WIFI NO	Not yet manufactured	
Z018757	AGILIA SP MC WIFI DK	25149979	
Z018760	AGILIA SP MC WIFI IT	25149979	
Z018762	AGILIA SP MC WIFI GR	25359480	
Z018770	AGILIA SP MC WIFI NL	25149979	
Z018779	AGILIA SP MC WIFI ID	Not yet manufactured	
Z018780	AGILIA SP MC WIFI ES	24997561	
Z018789	AGILIA SP MC WIFI ISE	25170079	
Z018791	AGILIA SP MC WIFI ZA	25170039	

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Z018792	AGILIA SP MC WIFI AU	From 24964895 to 24964924 And From 25380601	
Z018793	AGILIA SP MC WIFI PL	25381696	
Z018794	AGILIA SP MC WIFI TW	Not yet manufactured	
Z018795	AGILIA SP MC WIFI KR	Not yet manufactured	
Z018797	AGILIA SP MC WIFI IN	25264293	

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AGILIA SP TIVA

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z018800	AGILIA SP TIVA	25295790	4052682AIV01012bCF000ACG
Z018801*	AGILIA SP TIVA	25890402	
Z018810	AGILIA SP TIVA FR	25149979	
Z018812	AGILIA SP TIVA NOA	25294956	
Z018820	AGILIA SP TIVA DE	24964865	
Z018830	AGILIA SP TIVA GB	From 24845937 to 24845966 And From 24997083	
Z018831	AGILIA SP TIVA MEA	25057056	
Z018832	AGILIA SP TIVA MX	Not yet manufactured	
Z018836	AGILIA SP TIVA TH	Not yet manufactured	
Z018837	AGILIA SP TIVA MY	Not yet manufactured	
Z018839	AGILIA SP TIVA VN	Not yet manufactured	
Z018840	AGILIA SP TIVA BR	25264353	
Z018842	AGILIA SP TIVA AR	25472009	
Z018843	AGILIA SP TIVA PT	25239813	
Z018844	AGILIA SP TIVA SK	25449952	
Z018845	AGILIA SP TIVA HU	25359480	
Z018847	AGILIA SP TIVA TR	25449952	
Z018848	AGILIA SP TIVA RO	25359480	
Z018849	AGILIA SP TIVA BG	25359480	
Z018850	AGILIA SP TIVA SE	25149979	
Z018851	AGILIA SP TIVA FI	24997561	
Z018852	AGILIA SP TIVA SI	Not yet manufactured	
Z018853	AGILIA SP TIVA HR	25447870	
Z018857	AGILIA SP TIVA DK	25149979	
Z018860	AGILIA SP TIVA IT	25149979	
Z018862	AGILIA SP TIVA GR	25359480	
Z018870	AGILIA SP TIVA NL	25149979	
Z018879	AGILIA SP TIVA ID	Not yet manufactured	
Z018880	AGILIA SP TIVA ES	24997561	
Z018881	AGILIA SP TIVA CL	25170039	
Z018883	AGILIA SP TIVA UY	Not yet manufactured	
Z018889	AGILIA SP TIVA ISE	25170079	

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Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z018891	AGILIA SP TIVA ZA	25170039	
Z018892	AGILIA SP TIVA AU	From 24964895 to 24964924 And From 25380601	
Z018893	AGILIA SP TIVA PL	25381696	
Z018894	AGILIA SP TIVA TW	Not yet manufactured	
Z018895	AGILIA SP TIVA KR	Not yet manufactured	
Z018897	AGILIA SP TIVA IN	25264293	

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AGILIA SP TIVA WIFI

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z018900	AGILIA SP TIVA WIFI	25295790	4052682AIV01012bCF000ACG
Z018901*	AGILIA SP TIVA WIFI	25890662	
Z018910	AGILIA SP TIVA WIFI FR	25149979	
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	
Z018932	AGILIA SP TIVA WIFI MX	Not yet manufactured	
Z018933	AGILIA SP TIVA WIFI PH	25449952	
Z018936	AGILIA SP TIVA WIFI TH	Not yet manufactured	
Z018937	AGILIA SP TIVA WIFI MY	Not yet manufactured	
Z018939	AGILIA SP TIVA WIFI VN	Not yet manufactured	
Z018940	AGILIA SP TIVA WIFI BR	25264353	
Z018942	AGILIA SP TIVA WIFI AR	25472009	
Z018944	AGILIA SP TIVA WIFI SK	25449952	
Z018945	AGILIA SP TIVA WIFI HU	25359480	
Z018946	AGILIA SP TIVA WIFI CZ	25449436	
Z018948	AGILIA SP TIVA WIFI RO	25359480	
Z018950	AGILIA SP TIVA WIFI SE	25149979	
Z018951	AGILIA SP TIVA WIFI FI	24997561	
Z018955	AGILIA SP TIVA WIFI NO	Not yet manufactured	
Z018957	AGILIA SP TIVA WIFI DK	25149979	
Z018960	AGILIA SP TIVA WIFI IT	25149979	
Z018962	AGILIA SP TIVA WIFI GR	25359480	
Z018970	AGILIA SP TIVA WIFI NL	25149979	
Z018979	AGILIA SP TIVA WIFI ID	Not yet manufactured	
Z018980	AGILIA SP TIVA WIFI ES	24997561	
Z018989	AGILIA SP TIVA WIFI ISE	25170079	
Z018991	AGILIA SP TIVA WIFI ZA	25170039	
Z018992	AGILIA SP TIVA WIFI AU	From 24964895 to 24964924 And From 25380601	
Z018993	AGILIA SP TIVA WIFI PL	25381696	
Z018994	AGILIA SP TIVA WIFI TW	Not yet manufactured	

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Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z018997	AGILIA SP TIVA WIFI IN	25264293	

** 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.*

