
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 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 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.

Template for EU Declaration of Conformity with article list

**Attachment to EU DECLARATION OF CONFORMITY****SYRINGE INFUSION PUMP****AGILIA SP**

Article Number	Product Name	Basic UDI-DI	Intended Purpose	Serial Number/Batch Number
Z018500	AGILIA SP	4052682AIV01012bCF000ACG	Infusion Pumps and Accessories for Administration of Fluids	24963951
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
Z018558	AGILIA SP UA			25983296
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

Template for EU Declaration of Conformity with article list

Article Number	Product Name	Basic UDI-DI	Intended Purpose	Serial Number/Batch Number
Z018589**	AGILIA SP ISE			25170079
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

Template for EU Declaration of Conformity with article list

SYRINGE INFUSION PUMP**AGILIA SP MC**

Article Number	Product Name	Basic UDI-DI	Intended Purpose	Serial Number/Batch Number
Z018600	AGILIA SP MC	4052682AIV01012bCF000ACG	Infusion Pumps and Accessories for Administration of Fluids	24963951
Z018601**	AGILIA SP MC			25868794
Z018610**	AGILIA SP MC FR			26047269
Z018612**	AGILIA SP MC NOA			25294956
Z018620	AGILIA SP MC DE			24964865
Z018631**	AGILIA SP MC MEA			26047355
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
Z018658	AGILIA SP MC UA			24904775
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

Template for EU Declaration of Conformity with article list

Article Number	Product Name	Basic UDI-DI	Intended Purpose	Serial Number/Batch Number
Z018681	AGILIA SP MC CL			25170039
Z018683**	AGILIA SP MC UY			Not yet manufactured
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

Template for EU Declaration of Conformity with article list

SYRINGE INFUSION PUMP

AGILIA SP MC WIFI

Article Number	Product Name	Basic UDI-DI	Intended Purpose	Serial Number / Batch Number
Z018700	AGILIA SP MC WIFI	4052682AIV01012bCF000ACG	Infusion Pumps and Accessories for Administration of Fluids	25449951
Z018701*	AGILIA SP MC WIFI			25868764
Z018710**	AGILIA SP MC WIFI FR			26047299
Z018712**	AGILIA SP MC WIFI NOA			25294956
Z018720	AGILIA SP MC WIFI DE			24964865
Z018730**	AGILIA SP MC WIFI GB			Not yet manufactured
Z018731**	AGILIA SP MC WIFI MEA			25057056
Z018732*	AGILIA SP MC WIFI MX*			26198122
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 VN*			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

Template for EU Declaration of Conformity with article list

Article Number	Product Name	Basic UDI-DI	Intended Purpose	Serial Number/Batch Number
Z018757	AGILIA SP MC WIFI DK			25149979
Z018758	AGILIA SP MC WIFI UA			Not yet manufactured
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
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

Template for EU Declaration of Conformity with article list

SYRINGE INFUSION PUMP**AGILIA SP TIVA**

Article Number	Product Name	Basic UDI-DI	Intended Purpose	Serial Number / Batch Number
Z018800	AGILIA SP TIVA	4052682AIV01012bCF000ACG	Infusion Pumps and Accessories for Administration of Fluids	25295790
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			Not yet manufactured
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
Z018858	AGILIA SP TIVA UA			25983297
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

Template for EU Declaration of Conformity with article list

Article Number	Product Name	Basic UDI-DI	Intended Purpose	Serial Number/ Batch Number
Z018881	AGILIA SP TIVA CL			25170039
Z018883**	AGILIA SP TIVA UY			26047388
Z018889**	AGILIA SP TIVA ISE			25170079
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

Template for EU Declaration of Conformity with article list

SYRINGE INFUSION PUMP

AGILIA SP TIVA WIFI

Article Number	Product Name	Basic UDI-DI	Intended Purpose	Serial Number/Batch Number
Z018900	AGILIA SP TIVA WIFI	4052682AIV01012bCF000ACG	Infusion Pumps and Accessories for Administration of Fluids	25295790
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			Not yet manufactured
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
Z018958	AGILIA SP TIVA WIFI UA			Not yet manufactured
Z018960	AGILIA SP TIVA WIFI IT			25149979

Template for EU Declaration of Conformity with article list

Article Number	Product Name	Basic UDI-DI	Intended Purpose	Serial Number/Batch Number
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
Z018997	AGILIA SP TIVA WIFI IN*			25264293

Note: Device without "*" is device with embedded software version 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).

