

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 range: 24963951

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



Attachment to EU DECLARATION OF CONFORMITY

SYRINGE INFUSION PUMP

AGILIA SP

Article number	Product name
Z018500	AGILIA SP
Z018501**	AGILIA SP
Z018510*	AGILIA SP FR
Z018512*	AGILIA SP NOA
Z018520	AGILIA SP DE
Z018531*	AGILIA SP MEA
Z018532	AGILIA SP MX
Z018536	AGILIA SP TH
Z018537	AGILIA SP MY
Z018539	AGILIA SP VN
Z018540	AGILIA SP BR
Z018542	AGILIA SP AR
Z018543	AGILIA SP PT
Z018544	AGILIA SP SK
Z018547*	AGILIA SP TR
Z018548	AGILIA SP RO
Z018549	AGILIA SP BG
Z018550	AGILIA SP SE
Z018552	AGILIA SP SI
Z018553	AGILIA SP HR
Z018558	AGILIA SP UA
Z018560	AGILIA SP IT
Z018562	AGILIA SP GR
Z018564	AGILIA SP CY
Z018570	AGILIA SP NL
Z018579*	AGILIA SP ID
Z018580	AGILIA SP ES
Z018583*	AGILIA SP UY
Z018589*	AGILIA SP ISE
Z018591	AGILIA SP ZA
Z018592	AGILIA SP AU
Z018593	AGILIA SP PL
Z018594	AGILIA SP TW
Z018595	AGILIA SP KR
Z018597	AGILIA SP IN

Valid starting with the above date until product change

Doc ref: FKBZ-DT0122_DEC_ROHS-13 - page 2 of 6

FKBZ-D040509-1

AGILIA SP MC

Article number	Product name
Z018600	AGILIA SP MC
Z018601**	AGILIA SP MC
Z018610*	AGILIA SP MC FR
Z018612*	AGILIA SP MC NOA
Z018620	AGILIA SP MC DE
Z018631*	AGILIA SP MC MEA
Z018632	AGILIA SP MC MX
Z018636	AGILIA SP MC TH
Z018637	AGILIA SP MC MY
Z018639	AGILIA SP MC VN
Z018640	AGILIA SP MC BR
Z018641	AGILIA SP MC CO
Z018642	AGILIA SP MC AR
Z018643	AGILIA SP MC PT
Z018644	AGILIA SP MC SK
Z018645	AGILIA SP MC HU
Z018646	AGILIA SP MC CZ
Z018647*	AGILIA SP MC TR
Z018648	AGILIA SP MC RO
Z018649	AGILIA SP MC BG
Z018650	AGILIA SP MC SE
Z018651	AGILIA SP MC FI
Z018652	AGILIA SP MC SI
Z018653	AGILIA SP MC HR
Z018655	AGILIA SP MC NO
Z018657	AGILIA SP MC DK
Z018658	AGILIA SP MC UA
Z018660	AGILIA SP MC IT
Z018662	AGILIA SP MC GR
Z018664	AGILIA SP MC CY
Z018670	AGILIA SP MC NL
Z018679*	AGILIA SP MC ID
Z018680	AGILIA SP MC ES
Z018681	AGILIA SP MC CL
Z018683*	AGILIA SP MC UY
Z018689*	AGILIA SP MC ISE
Z018691	AGILIA SP MC ZA
Z018692	AGILIA SP MC AU
Z018693	AGILIA SP MC PL
Z018694	AGILIA SP MC TW
Z018695	AGILIA SP MC KR
Z018697	AGILIA SP MC IN

Valid starting with the above date until product change

Doc ref: FKBZ-DT0122_DEC_ROHS-13 - page 3 of 6

FKBZ-D040509-1

AGILIA SP MC WIFI

Article number	Product name
Z018700	AGILIA SP MC WIFI
Z018701**	AGILIA SP MC WIFI
Z018710*	AGILIA SP MC WIFI FR
Z018712*	AGILIA SP MC WIFI NOA
Z018720	AGILIA SP MC WIFI DE
Z018730*	AGILIA SP MC WIFI GB
Z018731*	AGILIA SP MC WIFI MEA
Z018732	AGILIA SP MC WIFI MX
Z018733	AGILIA SP MC WIFI PH
Z018736	AGILIA SP MC WIFI TH
Z018737	AGILIA SP MC WIFI MY
Z018738	AGILIA SP MC WIFI SG
Z018739	AGILIA SP MC WIFI VN
Z018740	AGILIA SP MC WIFI BR
Z018741	AGILIA SP MC WIFI CO
Z018742	AGILIA SP MC WIFI AR
Z018744	AGILIA SP MC WIFI SK
Z018745	AGILIA SP MC WIFI HU
Z018746	AGILIA SP MC WIFI CZ
Z018748	AGILIA SP MC WIFI RO
Z018750	AGILIA SP MC WIFI SE
Z018751	AGILIA SP MC WIFI FI
Z018752	AGILIA SP MC WIFI SI
Z018755	AGILIA SP MC WIFI NO
Z018757	AGILIA SP MC WIFI DK
Z018758	AGILIA SP MC WIFI UA
Z018760	AGILIA SP MC WIFI IT
Z018762	AGILIA SP MC WIFI GR
Z018770	AGILIA SP MC WIFI NL
Z018779*	AGILIA SP MC WIFI ID
Z018780	AGILIA SP MC WIFI ES
Z018789*	AGILIA SP MC WIFI ISE
Z018791	AGILIA SP MC WIFI ZA
Z018792	AGILIA SP MC WIFI AU
Z018793	AGILIA SP MC WIFI PL
Z018794	AGILIA SP MC WIFI TW
Z018795	AGILIA SP MC WIFI KR
Z018797	AGILIA SP MC WIFI IN

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Doc ref: FKBZ-DT0122_DEC_ROHS-13 - page 4 of 6

FKBZ-D040509-1

AGILIA SP TIVA

Article number	Product name
Z018800	AGILIA SP TIVA
Z018801**	AGILIA SP TIVA
Z018810*	AGILIA SP TIVA FR
Z018812*	AGILIA SP TIVA NOA
Z018820	AGILIA SP TIVA DE
Z018830*	AGILIA SP TIVA GB
Z018831*	AGILIA SP TIVA MEA
Z018832	AGILIA SP TIVA MX
Z018836	AGILIA SP TIVA TH
Z018837	AGILIA SP TIVA MY
Z018839	AGILIA SP TIVA VN
Z018840	AGILIA SP TIVA BR
Z018842	AGILIA SP TIVA AR
Z018843	AGILIA SP TIVA PT
Z018844	AGILIA SP TIVA SK
Z018845	AGILIA SP TIVA HU
Z018847*	AGILIA SP TIVA TR
Z018848	AGILIA SP TIVA RO
Z018849	AGILIA SP TIVA BG
Z018850	AGILIA SP TIVA SE
Z018851	AGILIA SP TIVA FI
Z018852	AGILIA SP TIVA SI
Z018853	AGILIA SP TIVA HR
Z018857	AGILIA SP TIVA DK
Z018858	AGILIA SP TIVA UA
Z018860	AGILIA SP TIVA IT
Z018862	AGILIA SP TIVA GR
Z018870	AGILIA SP TIVA NL
Z018879*	AGILIA SP TIVA ID
Z018880	AGILIA SP TIVA ES
Z018881	AGILIA SP TIVA CL
Z018883*	AGILIA SP TIVA UY
Z018889*	AGILIA SP TIVA ISE
Z018891	AGILIA SP TIVA ZA
Z018892	AGILIA SP TIVA AU
Z018893	AGILIA SP TIVA PL
Z018894	AGILIA SP TIVA TW
Z018895	AGILIA SP TIVA KR
Z018897	AGILIA SP TIVA IN

Valid starting with the above date until product change

Doc ref: FKBZ-DT0122_DEC_ROHS-13 - page 5 of 6

FKBZ-D040509-1

AGILIA SP TIVA WIFI

Article number	Product name
Z018900	AGILIA SP TIVA WIFI
Z018901**	AGILIA SP TIVA WIFI
Z018910*	AGILIA SP TIVA WIFI FR
Z018920	AGILIA SP TIVA WIFI DE
Z018930*	AGILIA SP TIVA WIFI GB
Z018931*	AGILIA SP TIVA WIFI MEA
Z018932	AGILIA SP TIVA WIFI MX
Z018933	AGILIA SP TIVA WIFI PH
Z018936	AGILIA SP TIVA WIFI TH
Z018937	AGILIA SP TIVA WIFI MY
Z018939	AGILIA SP TIVA WIFI VN
Z018940	AGILIA SP TIVA WIFI BR
Z018942	AGILIA SP TIVA WIFI AR
Z018944	AGILIA SP TIVA WIFI SK
Z018945	AGILIA SP TIVA WIFI HU
Z018946	AGILIA SP TIVA WIFI CZ
Z018948	AGILIA SP TIVA WIFI RO
Z018950	AGILIA SP TIVA WIFI SE
Z018951	AGILIA SP TIVA WIFI FI
Z018955	AGILIA SP TIVA WIFI NO
Z018957	AGILIA SP TIVA WIFI DK
Z018958	AGILIA SP TIVA WIFI UA
Z018960	AGILIA SP TIVA WIFI IT
Z018962	AGILIA SP TIVA WIFI GR
Z018970	AGILIA SP TIVA WIFI NL
Z018979*	AGILIA SP TIVA WIFI ID
Z018980	AGILIA SP TIVA WIFI ES
Z018989*	AGILIA SP TIVA WIFI ISE
Z018991	AGILIA SP TIVA WIFI ZA
Z018992	AGILIA SP TIVA WIFI AU
Z018993	AGILIA SP TIVA WIFI PL
Z018994	AGILIA SP TIVA WIFI TW
Z018997	AGILIA SP TIVA WIFI IN

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).