
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
Volumetric Infusion Pump
Infusion instrument

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 VP range: Rule 12, Class IIb
Drop Sensor: Rule 9, 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/ Brezins, on <i>23 July, 2024</i>	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

EU Declaration of Conformity with article list



Attachment to EU DECLARATION OF CONFORMITY

VOLUMETRIC INFUSION PUMP

AGILIA VP

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z019500	AGILIA VP	25471277	4052682AIV02012bCF000ADF
Z019501*	AGILIA VP	25892814	
Z019510*	AGILIA VP FR	Not yet manufactured	
Z019512*	AGILIA VP NOA	Not yet manufactured	
Z019520	AGILIA VP DE	24999406	
Z019531*	AGILIA VP MEA	Not yet manufactured	
Z019532	AGILIA VP MX	Not yet manufactured	
Z019536	AGILIA VP TH	Not yet manufactured	
Z019537	AGILIA VP MY	Not yet manufactured	
Z019539	AGILIA VP VN	Not yet manufactured	
Z019540	AGILIA VP BR	25265827	
Z019542	AGILIA VP AR	25471757	
Z019543	AGILIA VP PT	Not yet manufactured	
Z019544	AGILIA VP SK	25472493	
Z019547*	AGILIA VP TR	Not yet manufactured	
Z019548	AGILIA VP RO	25353980	
Z019549	AGILIA VP BG	25353980	
Z019550	AGILIA VP SE	25144362	
Z019553	AGILIA VP HR	25449839	
Z019555	AGILIA VP NO	Not yet manufactured	
Z019556	AGILIA VP RU	Not yet manufactured	
Z019557	AGILIA VP DK	25144362	
Z019560	AGILIA VP IT	25144362	
Z019562	AGILIA VP GR	25353980	
Z019564	AGILIA VP CY	25353980	
Z019570	AGILIA VP NL	25144362	
Z019579*	AGILIA VP ID	Not yet manufactured	

EU Declaration of Conformity with article list

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z019580	AGILIA VP ES	24967953	
Z019583*	AGILIA VP UY	Not yet manufactured	
Z019589*	AGILIA VP ISE	Not yet manufactured	
Z019592	AGILIA VP AU	25352679	
Z019593	AGILIA VP PL	Not yet manufactured	
Z019597	AGILIA VP IN	25298678	

EU Declaration of Conformity with article list

AGILIA VP MC

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z019600	AGILIA VP MC	25471277	4052682AIV02012bCF000ADF
Z019601*	AGILIA VP MC	25890575	
Z019610*	AGILIA VP MC FR	26042815	
Z019612*	AGILIA VP MC NOA	Not yet manufactured	
Z019620	AGILIA VP MC DE	24999406	
Z019631*	AGILIA VP MC MEA	Not yet manufactured	
Z019632	AGILIA VP MC MX	Not yet manufactured	
Z019636	AGILIA VP MC TH	Not yet manufactured	
Z019637	AGILIA VP MC MY	Not yet manufactured	
Z019639	AGILIA VP MC VN	Not yet manufactured	
Z019640	AGILIA VP MC BR	25265827	
Z019641	AGILIA VP MC CO	25239749	
Z019642	AGILIA VP MC AR	25471757	
Z019643	AGILIA VP MC PT	Not yet manufactured	
Z019644	AGILIA VP MC SK	25472493	
Z019645	AGILIA VP MC HU	25353980	
Z019646	AGILIA VP MC CZ	25470937	
Z019647*	AGILIA VP MC TR	Not yet manufactured	
Z019648	AGILIA VP MC RO	25353980	
Z019649	AGILIA VP MC BG	25353980	
Z019650	AGILIA VP MC SE	25144362	
Z019651	AGILIA VP MC FI	24967953	
Z019652	AGILIA VP MC SI	Not yet manufactured	
Z019653	AGILIA VP MC HR	25449839	
Z019656	AGILIA VP MC RU	Not yet manufactured	
Z019657	AGILIA VP MC DK	25144362	
Z019660	AGILIA VP MC IT	25144362	
Z019662	AGILIA VP MC GR	25353980	
Z019664	AGILIA VP MC CY	25353980	
Z019670	AGILIA VP MC NL	25144362	
Z019679*	AGILIA VP MC ID	Not yet manufactured	
Z019680	AGILIA VP MC ES	24967953	
Z019681	AGILIA VP MC CL	25144452	
Z019683*	AGILIA VP MC UY	Not yet manufactured	

EU Declaration of Conformity with article list

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z019689*	AGILIA VP MC ISE	Not yet manufactured	
Z019691	AGILIA VP MC ZA	25144452	
Z019692	AGILIA VP MC AU	25352679	
Z019693	AGILIA VP MC PL	Not yet manufactured	
Z019694	AGILIA VP MC TW	Not yet manufactured	
Z019697	AGILIA VP MC IN	25298678	

EU Declaration of Conformity with article list

AGILIA VP MC WIFI

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z019700	AGILIA VP MC WIFI	25298525	4052682AIV02012bCF000ADF
Z019701*	AGILIA VP MC WIFI	25890665	
Z019710*	AGILIA VP MC WIFI FR	Not yet manufactured	
Z019712*	AGILIA VP MC WIFI NOA	Not yet manufactured	
Z019720	AGILIA VP MC WIFI DE	24999406	
Z019730*	AGILIA VP MC WIFI GB	Not yet manufactured	
Z019731*	AGILIA VP MC WIFI MEA	26042706	
Z019732	AGILIA VP MC WIFI MX	Not yet manufactured	
Z019733	AGILIA VP MC WIFI PH	25472493	
Z019736	AGILIA VP MC WIFI TH	Not yet manufactured	
Z019737	AGILIA VP MC WIFI MY	Not yet manufactured	
Z019738	AGILIA VP MC WIFI SG	Not yet manufactured	
Z019739	AGILIA VP MC WIFI VN	Not yet manufactured	
Z019740	AGILIA VP MC WIFI BR	25265827	
Z019741	AGILIA VP MC WIFI CO	25239749	
Z019742	AGILIA VP MC WIFI AR	25471757	
Z019744	AGILIA VP MC WIFI SK	25472493	
Z019745	AGILIA VP MC WIFI HU	25353980	
Z019746	AGILIA VP MC WIFI CZ	25470937	
Z019748	AGILIA VP MC WIFI RO	25353980	
Z019750	AGILIA VP MC WIFI SE	25144362	
Z019751	AGILIA VP MC WIFI FI	24967953	
Z019755	AGILIA VP MC WIFI NO	Not yet manufactured	
Z019756	AGILIA VP MC WIFI RU	Not yet manufactured	
Z019757	AGILIA VP MC WIFI DK	25144362	
Z019760	AGILIA VP MC WIFI IT	25144362	
Z019762	AGILIA VP MC WIFI GR	25353980	
Z019770	AGILIA VP MC WIFI NL	25144362	
Z019779*	AGILIA VP MC WIFI ID	Not yet manufactured	
Z019780	AGILIA VP MC WIFI ES	24967953	
Z019789*	AGILIA VP MC WIFI ISE	Not yet manufactured	
Z019791	AGILIA VP MC WIFI ZA	25144452	
Z019792	AGILIA VP MC WIFI AU	25352679	
Z019793	AGILIA VP MC WIFI PL	Not yet manufactured	

EU Declaration of Conformity with article list

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z019794	AGILIA VP MC WIFI TW	Not yet manufactured	
Z019797	AGILIA VP MC WIFI IN	25298678	

** 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.*

EU Declaration of Conformity with article list

INFUSION INSTRUMENT

Drop Sensor

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z073205	Drop Sensor	25867907	4052682AND37012bHF00006F