
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
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/

Brézins, on *Dec. 20, 2024*

Name (printed letters), position and signature of authorized person/

Laurent KELLER
Regulatory Affairs Manager



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Valid starting with the original date of the document until product change.



Attachment to EU DECLARATION OF CONFORMITY

VOLUMETRIC INFUSION PUMP

AGILIA VP

Article Number	Product Name	Basic UDI-DI	Intended Purpose	Serial Number/Batch Number
Z019500	AGILIA VP	4052682AIV02012bCF000ADF	Infusion Pumps and Accessories for Administration of Fluids	25471277
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
Z019558	AGILIA VP UA			25686409
Z019560	AGILIA VP IT			25144362
Z019562	AGILIA VP GR			25353980
Z019564	AGILIA VP CY			25353980

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Article Number	Product Name	Basic UDI-DI	Intended Purpose	Serial Number/Batch Number
Z019570	AGILIA VP NL			25144362
Z019579*	AGILIA VP ID			Not yet manufactured
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

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VOLUMETRIC INFUSION PUMP

AGILIA VP MC

Article Number	Product Name	Basic UDI-DI	Intended Purpose	Serial Number/ Batch Number
Z019600	AGILIA VP MC	4052682AIV02012bCF000ADF	Infusion Pumps and Accessories for Administration of Fluids	25471277
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
Z019658	AGILIA VP MC UA			24845745
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		

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Article Number	Product Name	Basic UDI-DI	Intended Purpose	Serial Number/Batch Number
Z019681	AGILIA VP MC CL			25144452
Z019683*	AGILIA VP MC UY			Not yet manufactured
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

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VOLUMETRIC INFUSION PUMP

AGILIA VP MC WIFI

Article Number	Product Name	Basic UDI-DI	Intended Purpose	Serial Number/Batch Number
Z019700	AGILIA VP MC WIFI	4052682AIV02012bCF000ADF	Infusion Pumps and Accessories for Administration of Fluids	25298525
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		

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Article Number	Product Name	Basic UDI-DI	Intended Purpose	Serial Number/ Batch Number
Z019757	AGILIA VP MC WIFI DK			25144362
Z019758	AGILIA VP MC WIFI UA			Not yet manufactured
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
Z019794	AGILIA VP MC WIFI TW			Not yet manufactured
Z019797	AGILIA VP MC WIFI IN			25298678

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) or Plexus (D62 as Wi-Fi software version) Wi-Fi module.*

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INFUSION INSTRUMENT

Drop Sensor

Article Number	Product Name	Basic UDI-DI	Intended Purpose	Serial Number/ Batch Number
Z073205	Drop Sensor	4052682AND37012bHF00006F	Infusion Pumps and Accessories for Administration of Fluids	25867907