



**FRESENIUS  
KABI**

## **EC DECLARATION OF CONFORMITY**

*Déclaration de conformité UE / EU-Konformitätserklärung*

1- Device type / *Type d'appareil / Produktgruppe*

**AGILIA SP MC WIFI Range  
AGILIA SP TIVA WIFI Range**

From Serial number/ *Du numéro de série / Ab Seriennummer :*

**AGILIA SP range (WIFI) : 24964865**

2- Name and address of the manufacturer/ *Nom et adresse du fabricant/ Name und Anschrift des Herstellers*

**Fresenius Kabi AG, Else-Kröner-Str. 1, 61352 Bad Homburg, Germany**

3- This declaration of conformity is issued under the sole responsibility of the manufacturer.

*La présente déclaration de conformité est établie sous la seule responsabilité du fabricant.*

*Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller.*

4- Object of the declaration/ *Object de la déclaration/ Gegenstand der Erklärung*

See attached list / *Voir liste jointe / siehe seite 2-3*

5- The object of the declaration described above is in conformity with the relevant Union harmonization legislation and its transposition into national laws: / *L'objet de la déclaration décrit ci-dessus est conforme à la législation d'harmonisation de l'Union applicable et du texte transpose en loi nationale : / Der oben beschriebene Gegenstand der Erklärung erfüllt die einschlägigen Harmonisierungsrechtsvorschriften der Union und deren Umsetzung in nationale Gesetze übereinstimmen:*

- Radio Equipment Directive (RED) Directive 2014/53/EU

6- References to the relevant harmonized standards used of references to the other technical specifications in Which conformity is declared. / *Références des normes harmonisées pertinentes appliquées ou des autres spécifications techniques par rapport auxquelles la conformité est déclarée. / Angabe der einschlägigen harmonisierten Normen. Die zugrunde gelegt wurden. Order Angabe der anderen technischen Spezifikationen. Bezüglich derer die Konformität erklärt.*

### **RED**

<b>Reference</b>	<b>Title</b>
ETSI EN 300 328	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques
ETSI EN 301 893	Broadband Radio Access Networks (BRAN); 5 GHz high performance RLAN 5 GHz RLAN
ETSI EN 301 489-17	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard for ElectroMagnetic Compatibility
EN 62311: 2008	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0Hz – 300 GHz)

7- Notified Body Involved or Testing Organization(s) / *Organisme notifié impliqué ou organisme(s) de test/ Benannte Stelle beteiligt oder Prüfung Organisation(en)*

LCIE Bureau Veritas – Site de Fontenay aux Roses

33, avenue du Général Leclerc

92260 Fontenay-aux-Roses

France

8- Signed for and on behalf of/ *Signé par et au nom de/ Unterzeichnet für und im Namen von*

Place and date of issue/ *Lieu et date d'émission/*

*Ort und Datum der Ausstellung*

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

*Name (Blockschrift), Position and Unterschrift der autorisierten Person*

Brézins, On/Le *May 02, 2024*

Laurent KELLER  
Regulatory Affairs Manager

Valid starting with the above date until product change / *Valide depuis la date ci-dessus jusqu'à modification du produit /*  
*Gültig ab Ausstellungsdatum bis Produktänderung*




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## **EC DECLARATION OF CONFORMITY**

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### **AGILIA SP MC WIFI**

<i>Article number / Code article / Artikelnummer</i>	<i>Product name / Nom du produit / Pruduktname</i>	<i>Picture / Image / Bild</i>
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	
Z018760	AGILIA SP MC WIFI IT	
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	
Z018794	AGILIA SP MC WIFI TW	
Z018795	AGILIA SP MC WIFI KR	
Z018797	AGILIA SP MC WIFI IN	

### **Physical manufacturer**


**FRESENIUS VIAL S.A.S.**  
Le Grand Chemin  
38590 Brezins  
France

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Gültig ab Ausstellungsdatum bis Produktänderung*

# EC DECLARATION OF CONFORMITY

*Déclaration de conformité UE / EU-Konformitätserklärung*

## AGILIA SP TIVA WIFI

Article number / Code article / Artikelnummer	Product name / Nom du produit / Pruduktname	Picture / Image / Bild
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	
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	

### Physical manufacturer

FRESENIUS VIAL S.A.S.  
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\* 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.

