

EU Declaration of Conformity

Manufacturer according to Regulation 2017/745	Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt Germany		
Registration Number acc. to Art. 31 2017/745	DE-MF-000005701		
Product Name	aspirmatic®		
Basic UDI-DI Code acc. to Art. 26 2017/745 Intended Purpose	4032651BSC00000018AD D99 disinfectant for suction units		
Risk Class according to Regulation 2017/745	II a Annex VIII rule 16		
Standards applied	EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH		
Notified Body	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany No.: 0297		
Conformity Assessment Procedure according to Regulation 2017/745	Annex IX	Chapter I, II section 4 and III	
Certificates	Annex IX EN ISO 13485	004567 MDR2017Q 004567 MDR2017B 004567 MP2016	
Version	1-0		

Schülke & Mayr GmbH herewith declares that the device covered by this declaration is in conformity with the Regulation 2017/745 concerning medical devices.

Schülke & Mayr GmbH declares that Schülke & Mayr GmbH bears the sole responsibility for issuing this declaration

Norderstedt

EU Declaration of Conformity

Manufacturer according to Regulation 2017/745	Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt Germany
Registration Number acc. to Art. 31 2017/745	DE-MF-000005701
Product name	aspirmatic® cleaner
basic UDI-DI Code acc. to Art. 26 2017/745 Intended Purpose	4032651-BSC00000002-CM V9099 cleaning agent for suction units
Risk Class according to Regulation 2017/745	I annex VIII rule 1
Standards applied	EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH
Conformity Assessment Procedure according to Regulation 2017/745	annex II / III
Certificate	EN ISO 13485 004567 MP2016
Version	3-0

Schülke & Mayr GmbH herewith declares that the device covered by this declaration is in conformity with the Regulation 2017/745 concerning medical devices.

Schülke & Mayr GmbH declares that Schülke & Mayr GmbH bears the sole responsibility for issuing this Declaration

Norderstedt	15.08.2024 ppa.	15.08.2024 ppa.
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Director Innovation & Regulatory
Affairs

Chief Operating Officer

EU Declaration of Conformity

Manufacturer according to Regulation 2017/745	Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt Germany		
Registration Number acc. to Art. 31 2017/745	DE-MF-000005701		
Product Name	gigasept® Instru AF		
Basic UDI-DI Code acc. to Art. 26 2017/745	4032651BSC00000037AH Z12011385		
Intended Purpose	cleaning and disinfection agent for manual reprocessing of medical devices		
Risk Class according to Regulation 2017/745	II a	Annex VIII	rule 16
Standards applied	EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH		
Notified Body	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany No.: 0297		
Conformity Assessment Procedure according to Regulation 2017/745	Annex IX	Chapter I, II section 4 and III	
Certificates	Annex IX	004567 MDR2017Q 004567 MDR2017B EN ISO 13485 004567 MP2016	
Version	1-0		

Schülke & Mayr GmbH herewith declares that the device covered by this declaration is in conformity with the Regulation 2017/745 concerning medical devices.

Schülke & Mayr GmbH declares that Schülke & Mayr GmbH bears the sole responsibility for issuing this declaration

Norderstedt 15.06.2023 15.06.2023

Chief Commercial Officer

Chief Operating Officer

EU Declaration of Conformity

Manufacturer according to Regulation 2017/745	Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt Germany		
Registration Number acc. to Art. 31 2017/745	DE-MF-000005701		
Product Name	mikrozid® AF liquid		
Basic UDI-DI Code acc. to Art. 26 2017/745 Intended Purpose	4032651BSC000000209Y D0799 disinfectant and cleaner of medical device surfaces		
Risk Class according to Regulation 2017/745	II a Annex VIII rule 16		
Standards applied	EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH		
Notified Body	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany No.: 0297		
Conformity Assessment Procedure according to Regulation 2017/745	Annex IX	Chapter I, II section 4 and III	
Certificates	Annex IX	004567 MDR2017Q 004567 MDR2017B	
	EN ISO 13485	004567 MP2016	
Version	1-0		

Schülke & Mayr GmbH herewith declares that the device covered by this declaration is in conformity with the Regulation 2017/745 concerning medical devices.

Schülke & Mayr GmbH declares that Schülke & Mayr GmbH bears the sole responsibility for issuing this declaration

Norderstedt 15.06.2023

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Chief Commercial Officer

Chief Operating Officer

EU Declaration of Conformity

Manufacturer according to Regulation 2017/745	Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt Germany		
Registration Number acc. to Art. 31 2017/745	DE-MF-000005701		
Product Name	mikrozid® AF wipes		
Basic UDI-DI Code acc. to Art. 26 2017/745 Intended Purpose	4032651BSC000000209Y D0799 disinfectant and cleaner of medical device surfaces		
Risk Class according to Regulation 2017/745	II a annex VIII rule 16		
Standards applied	EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH		
Notified Body	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany No.: 0297		
Conformity Assessment Procedure according to Regulation 2017/745	annex IX	Chapter I, II section 4 and III	
Certificates	annex IX	004567 MDR2017Q 004567 MDR2017B	
	EN ISO 13485	004567 MP2016	
Version	1-0		

Schülke & Mayr GmbH herewith declares that the device covered by this declaration is in conformity with the Regulation 2017/745 concerning medical devices.

Schülke & Mayr GmbH declares that Schülke & Mayr GmbH bears the sole responsibility for issuing this declaration

Norderstedt	15.06.2023	15.06.2023
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EU Declaration of Conformity

Manufacturer according to Regulation 2017/745	Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt Germany		
Registration Number acc. to Art. 31 2017/745	DE-MF-000005701		
Product Name	mikrozid[®] sensitive wipes		
Basic UDI-DI Code acc. to Art. 26 2017/745 Intended Purpose	4032651BSC00000021A2 D99 disinfectant and cleaner of medical device surfaces		
Risk Class according to Regulation 2017/745	II a Annex VIII rule 16		
Standards applied	EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH		
Notified Body	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany No.: 0297		
Conformity Assessment Procedure according to Regulation 2017/745	Annex IX	Chapter I, II section 4 and III	
Certificates	Annex IX	004567 MDR2017Q 004567 MDR2017B	
	EN ISO 13485	004567 MP2016	
Version	1-0		

Schülke & Mayr GmbH herewith declares that the device covered by this declaration is in conformity with the Regulation 2017/745 concerning medical devices.

Schülke & Mayr GmbH declares that Schülke & Mayr GmbH bears the sole responsibility for issuing this declaration

Norderstedt 15.06.2023

15.06.2023

Schülke & Mayr GmbH
Chief Commercial Officer

Schülke & Mayr GmbH
Chief Operating Officer



EU declaration of conformity

<p>Manufacturer according to Regulation 2017/745</p>	<p>Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt Germany</p>
<p>Registration Number acc. to Art. 31 2017/745</p>	<p>DE-MF-000005701</p>
<p>Product name thermosept® X-tra enzymatic cleaner</p>	
<p>basic UDI-DI Code acc. to Art. 26 2017/745 Intended Purpose</p>	<p>4032651-BSC00000004-CT V0799 cleaning agent for automated reprocessing of medical devices</p>
<p>Risk Class according to Regulation 2017/745</p>	<p>I annex VIII rule 1</p>
<p>Standards applied</p>	<p>EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH</p>
<p>Conformity Assessment Procedure according to Regulation 2017/745</p>	
<p>certificate</p>	<p>annex IV / V EN ISO 13485 004567 MP2016</p>
<p>Version</p>	<p>1-0</p>

Schülke & Mayr GmbH herewith declares that the device covered by this declaration is in conformity with the Regulation 2017/745 concerning medical devices.

Schülke & Mayr GmbH declares that Schülke & Mayr GmbH bears the sole responsibility for issuing this Declaration

Norderstedt 01.06.2022

Schülke & Mayr GmbH
Chief Commercial Officer

Schülke & Mayr GmbH
Chief Operating Officer

This Declaration is valid until an updated version has been issued, but not longer than 26.06.2024

Gamintojo deklaracija

pateikta pagal Reglamentą (ES) 2023/607, kuriuo dėl tam tikroms medicinos priemonėms ir *in vitro* diagnostikos medicinos priemonėms taikomų pereinamojo laikotarpio nuostatų iš dalies keičiami Reglamentai (ES) 2017 /745 ir (ES) 2017/746, visų pirma dėl:

- sertifikatų, išduotų pagal Tarybos direktyvą 90/385/EEB dėl aktyviųjų implantuojamų medicinos priemonių (AIMPD) arba Tarybos direktyvą 93/42/EEB dėl medicinos priemonių (MPD) (toliau - direktyvos sertifikatai) galiojimo
ir
- priemonių ir mūsų, kaip jų gamintojų, atitikties tolesnio tiekimo rinkai ir naudojimo sąlygoms.

Gamintojo pavadinimas	Schulke CZ, s.r.o.
Gamintojo adresas ir kontaktiniai duomenys	Lidicka 445, Novy Bohumin 735 14 Bohumin Čekijos Respublika
Unikalasis registracijos numeris (SRN) (jei taikoma)	CZ-MF-000024068

Notifikuotosios įstaigos pavadinimas (jei taikoma)	BANDYMŲ IR SERTIFIKAVIMO INSTITUTAS
Notifikuotosios įstaigos numeris (jei taikoma)	1023
Direktyvos sertifikato, pagal kurį atliekamas šis patvirtinimas, numeris (jei taikoma)	19 0229 QS/NB rev. a
Direktyvos sertifikate nurodyta pradinė galiojimo pabaigos data iki galiojimo pratęsimo (jei taikoma)	2024.05.08.
Pratęsimo galiojimo / pereinamojo laikotarpio pabaigos data	2028.12.31.

Mes, kaip gamintojai, pareiškiame, kad prisiimame visą atsakomybę už tai, kad:

- yra įvykdytos pirmiau nurodyto Direktyvos sertifikato (arba, jei sertifikatų yra keletas, žr. pridedamą sąrašą) teisinio galiojimo pratęsimo sąlygos, kaip reikalaujama Medicinos priemonių reglamento (MPR) 120 straipsnio 2 dalyje, *ir*
- pridedamame sąrašė išvardytos priemonės ir mes, kaip jų gamintojai, atitinkame MPR 120 straipsnio 3c dalyje išvardytas tolesnio tiekimo rinkai ir naudojimo sąlygas,

t.y. yra įvykdytos toliau nurodytos sąlygos:

- Pirmiau arba pridedamame sąrašė nurodytas Direktyvos sertifikatas (-ai)
 - Direktyvos sertifikatas (-ai), taikomas (-i) į sąrašą įtrauktai (-oms) priemonei (-ėms), išduotas (-i) po 2017 m. gegužės 25 d., galiojo 2021 m. gegužės 26 d. ir vėliau nebuvo panaikintas (-i).
 - Nustoja galioti / nustojo galioti po 2023 m. kovo 20 d.:
 - oficialią (-ias) paraišką (-as) notifikuotajai įstaigai pagal MDR VII priedo 4.3 skirsnio pirmą pastraipą dėl atitikties vertinimo pateikėme arba pateiksime ne vėliau kaip 2024 m. gegužės 26 d. dėl pridedamame sąrašė nurodytos (-ų) priemonės (-ų) arba jos (-ų) pakaitalo (-ų) ir iki 2024 m. rugsėjo 26 d. pagal MDR VII priedo 4.3 skirsnio antrą pastraipą bus pasirašytas (-i) rašytinis (-iai) susitarimas (-ai).

- Kokybės valdymo sistema (KVS)
 - Įdiegta KVS pagal MPR 10 straipsnio 9 dalį.

- Priedamame sąrašė išvardytos priemonės
 - Priemonės toliau atitinka MPD reikalavimus.
 - Nėra jokių reikšmingų dizaino ir numatomos paskirties pakeitimų.
 - Priemonės nekelia nepriimtino pavojaus pacientų, naudotojų ar kitų asmenų sveikatai ar saugai arba kitiems visuomenės sveikatos apsaugos aspektams.

Pasirašyta gamintojo vardu:

Schulke CZ, s.r.o.

Bohumín, 2024.05.22

Pavardė ir pareigos: inž. Jarmila

Kokybės ir reglamentavimo reik

Kontaktiniai duomenys:

jarmila.fafilkova@schulke.co

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Priemonių sąrašas

Pirmiau pateikta gamintojo deklaracija galioja šioms priemonėms:

Priemonės duomenys ¹² (pvz., priemonės pavadinimas, grupės pavadinimas, modelis arba katalogo numeris)	Direktyvos sertifikato pagal kurį atliekamas šis patvirtinimas, numeris (jei taikoma)	Direktyvos sertifikate nurodyta pradinė galiojimo pabaigos data iki galiojimo pratęsimo (jei taikoma)	Notifikuotosios įstaigos, išdavusios Direktyvos sertifikatą, pavadinimas ir numeris (jei taikoma)	Notifikuotosios įstaigos, kuriai pateikta paraiška pagal MPR / su kuria pasirašyta sutartis, pavadinimas ir numeris (jei taikoma)	Pratęsto sertifikato pereinamojo laikotarpio pabaigos data	Pakaitinė (-s) priemonė (-s) (jei taikoma)
desam [®] effect+	19 0229 QS/NB rev. a	2024.05.08.	BANDYMŲ IR SERTIFIKAVIMO INSTITUTAS NB 1023	BANDYMŲ IR SERTIFIKAVIMO INSTITUTAS NB 1023	2028.12.31.	netaikoma
desam [®] OX	19 0229 QS/NB rev. a	2024.05.08.	BANDYMŲ IR SERTIFIKAVIMO INSTITUTAS NB 1023	BANDYMŲ IR SERTIFIKAVIMO INSTITUTAS NB 1023	2028.12.31.	netaikoma
gigazyme [®] actifoam+	19 0229 QS/NB rev. a	2024.05.08.	BANDYMŲ IR SERTIFIKAVIMO INSTITUTAS NB 1023	BANDYMŲ IR SERTIFIKAVIMO INSTITUTAS NB 1023	2028.12.31.	netaikoma
discleen [®] extra	19 0229 QS/NB rev. a	2024.05.08.	BANDYMŲ IR SERTIFIKAVIMO INSTITUTAS NB 1023	BANDYMŲ IR SERTIFIKAVIMO INSTITUTAS NB 1023	2028.12.31.	netaikoma
chirosan [®] plus	19 0229 QS/NB rev. a	2024.05.08.	BANDYMŲ IR SERTIFIKAVIMO INSTITUTAS NB 1023	BANDYMŲ IR SERTIFIKAVIMO INSTITUTAS NB 1023	2028.12.31.	netaikoma
discleen [®] endo PAA	19 0229 QS/NB rev. a	2024.05.08.	BANDYMŲ IR SERTIFIKAVIMO INSTITUTAS NB 1023	BANDYMŲ IR SERTIFIKAVIMO INSTITUTAS NB 1023	2028.12.31.	netaikoma

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Schulke CZ, s.r.o.
Manufacturer address and contact details.	Lidická 445, Nový Bohumín 735 14 Bohumín The Czech Republic
Single Registration Number (SRN) (if available)	CZ-MF-000024068

Notified body name (if applicable)	INSTITUTE FOR TESTING AND CERTIFICATION
Notified body number (if applicable)	1023
Directive Certificate number(s) to which this confirmation is made (if applicable)	19 0229 QS/NB rev. a
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	08.05.2024
End date of extended validity/transition period	31.12.2028

We, as the manufacturer declare under our sole responsibility:

- for the above listed Directive Certificate (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed device(s) in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- Directive Certificate(s) as listed above or in the attached schedule
 - Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.
 - Expired/expires *after* 20 March 2023:
 - Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- Quality Management System (QMS)
 - A QMS in accordance with Article 10(9) MDR is in place.
- Device(s) as listed in the attached schedule
 - The devices continue to comply with the MDD.
 - There are no significant changes in the design and intended purpose.
 - The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Schulke CZ, s.r.o.

Bohumín, 22.05.2024

Print Name, Title: Ing. Jarmila Fafilková

Quality and Regulatory Affairs Manage

Contact Details: jarmila.fafilkova@schulke.cz

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ke CZ, s.r.o.
, 735 81 Bohumín
h Republic
DIČ: CZ 243 01 779

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) ¹² (e.g., device name, family/group name device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
desam® effect +	19 0229 QS/NB rev. a	08.05. 2024	INSTITUTE FOR TESTING AND CERTIFICATION, NB 1023	INSTITUTE FOR TESTING AND CERTIFICATION, NB 1023	31.12.2028	n/a
desam® OX	19 0229 QS/NB rev. a	08.05. 2024	INSTITUTE FOR TESTING AND CERTIFICATION, NB 1023	INSTITUTE FOR TESTING AND CERTIFICATION NB 1023	31.12.2028	n/a
gigazyme® actifoam+	19 0229 QS/NB rev. a	08.05. 2024	INSTITUTE FOR TESTING AND CERTIFICATION NB 1023	INSTITUTE FOR TESTING AND CERTIFICATION NB 1023	31.12.2028	n/a
discleen® extra	19 0229 QS/NB rev. a	08.05. 2024	INSTITUTE FOR TESTING AND CERTIFICATION NB 1023	INSTITUTE FOR TESTING AND CERTIFICATION NB 1023	31.12.2028	n/a
chirosan® plus	19 0229 QS/NB rev. a	08.05. 2024	INSTITUTE FOR TESTING AND CERTIFICATION NB 1023	INSTITUTE FOR TESTING AND CERTIFICATION NB 1023	31.12.2028	n/a
discleen® endo PAA	19 0229 QS/NB rev. a	08.05. 2024	INSTITUTE FOR TESTING AND CERTIFICATION NB 1023	INSTITUTE FOR TESTING AND CERTIFICATION NB 1023	31.12.2028	n/a

Gamintojo deklaracija

pateikta pagal Reglamentą (ES) 2023/607, kuriuo dėl tam tikroms medicinos priemonėms ir *in vitro* diagnostikos medicinos priemonėms taikomų pereinamojo laikotarpio nuostatų iš dalies keičiami Reglamentai (ES) 2017/745 ir (ES) 2017/746, visų pirma dėl:

- sertifikatų, išduotų pagal Tarybos direktyvą 93/42/EEB dėl medicinos prietaisų (MPD) (toliau – Direktyvos sertifikatai), galiojimo, taip pat
- priemonių ir mūšų, kaip jų gamintojų, atitikties tolesnio tiekimo rinkai ir naudojimo sąlygoms.

Gamintojo pavadinimas	Schülke & Mayr GmbH
Gamintojo adresas ir kontaktiniai duomenys	Robert-Koch-Str. 2 22851 Norderstedt Vokietija
Unikalasis registracijos numeris	DE-MF-000005701

Notifikuotosios įstaigos pavadinimas	DQS Medizinprodukte GmbH
Notifikuotosios įstaigos numeris	0297
Direktyvos sertifikato, pagal kurį atliekamas šis patvirtinimas, numeris	004567 MR2
Direktyvos sertifikate nurodyta pradinė galiojimo pabaigos data iki galiojimo pratęsimo	2023 12 18
Pratęsto galiojimo / pereinamojo laikotarpio pabaigos data	2028 12 31

Mes, kaip gamintojai, pareiškiame, kad prisiimame visą atsakomybę už tai, kad:

- yra įvykdytos pirmiau nurodyto **Direktyvos sertifikato** teisinio galiojimo pratęsimo sąlygos, kaip reikalaujama MPR 120 straipsnio 2 dalyje, ir
- pridedame sąrašė išvardytos **priemonės** ir mes, kaip jų gamintojai, atitinkame MPR 120 straipsnio 3c dalyje išvardytas tolesnio tiekimo rinkai ir naudojimo sąlygas, t. y. yra įvykdytos toliau nurodytos sąlygos.

Schülke & Mayr GmbH

Robert-Koch-Str. 2 | 22851 Norderstedt | Pašto adresas: 22840 Norderstedt | Vokietija
Tel. +49 40 52100-0 | Faks. +49 40 52100-318
info@schuelke.com | www.schuelke.com
Numeris prekybos registre: Kylio apylinkės teismas, HRB 38 21 NO
Valdantieji direktoriai: Stefan Kukacka (pirmininkas), Hans-Christian Nehlsen

Banko informacija: Commerzbank AG Frankfurt/Main
BSC 200 400 00 | Sąskaitos Nr. 42 46 757 00
SWIFT-BIC: COBA DE FFXX | IBAN: DE20 2004 0000 0424 6757 00
PVM mokėtojo kodas: DE 81 2065369
Kreditoriaus identifikatorius: DE10ZZZ000000006191

➤ Pirmiau arba pridedamame sąraše nurodytas **Direktyvos sertifikatas**

- Direktivos sertifikatas, taikomas išvardytoms priemonėms, buvo išduotas po 2017 m. gegužės 25 d., galiojo 2021 m. gegužės 26 d. ir vėliau nebuvo panaikintas.

Nustoto galioti *po* 2023 m. kovo 20 d.

Oficialūs prašymai notifikuotajai įstaigai pagal MPR VII priedo 4.3 skirsnio pirmąją pastraipą dėl atitikties įvertinimo buvo pateikti dėl pridedamame sąraše išvardytų priemonių ir iki 2024 m. rugsėjo 26 d. bus pasirašyti rašytiniai susitarimai pagal MPR VII priedo 4.3 skirsnio antrąją pastraipą.

➤ **Kokybės valdymo sistema (KVS)**

Notifikuotoji įstaiga išdavė MPR reikalavimus atitinkančios KVS sertifikatą.

➤ **Pridedamame sąraše išvardytos priemonės**

- Priemonės vis dar atitinka MDD reikalavimus.
- Nėra jokių reikšmingų dizaino ir numatomos paskirties pakeitimų.
- Priemonės nekelia nepriimtino pavojaus pacientų, naudotojų ar kitų asmenų sveikatai ar saugai arba kitiems visuomenės sveikatos apsaugos aspektams.

Pasirašyta ga

Schülke & Mayr GmbH

Robert-Koch-Str. 2 | 22851 Norderstedt | Pašto adresas: 22840 Norderstedt | Vokietija
Tel. +49 40 52100-0 | Faks. +49 40 52100-318
info@schuelke.com | www.schuelke.com
Numeris prekybos registre: Kylio apylinkės teismas, HRB 38 21 NO
Valdantieji direktoriai: Stefan Kukacka (pirmininkas), Hans-Christian Nehlsen

Banko informacija: Commerzbank AG Frankfurt/Main
BSC 200 400 00 | Sąskaitos Nr. 42 46 757 00
SWIFT-BIC: COBA DE FFXXX | IBAN: DE20 2004 0000 0424 6757 00
PVM mokėtojo kodas: DE 81 2065369
Kreditoriaus identifikatorius: DE10ZZZ00000006191

Priemonių sąrašas

Pirmiau pateikta gamintojo deklaracija galioja šioms priemonėms:

Priemonės duomenys (pvz., priemonės pavadinimas, šeimos / grupės pavadinimas, priemonės modelis arba katalogo numeris)	Direktyvos sertifikato, pagal kurį atliekamas šis patvirtinimas, numeris	Direktyvos sertifikate nurodyta pradinė galiojimo pabaigos data iki galiojimo pratęsimo	Notifikuotosios įstaigos, išdavusios Direktyvos sertifikatą, pavadinimas ir numeris	Notifikuotosios įstaigos, kuriai pateikta paraiška pagal MPR / su kuria pasirašyta sutartis, pavadinimas ir numeris	Pratęsto galiojimo / pereinamojo laikotarpio pabaigos data	Pakaitinė (-ės) priemonė (-ės)
„ Thermosept® ED “	004567 MR2	2023 12 18	DQS Medizinprodukte GmbH 0297	DQS Medizinprodukte GmbH 0297	2028 12 31	netaikoma
„ Gigasept® FF “ (new) / „ Desimatic ID plus “	004567 MR2	2023 12 18	DQS Medizinprodukte GmbH 0297	DQS Medizinprodukte GmbH 0297	2028 12 31	netaikoma
„ Rotasept® “	004567 MR2	2023 12 18	DQS Medizinprodukte GmbH 0297	DQS Medizinprodukte GmbH 0297	2028 12 31	netaikoma

Schülke & Mayr GmbH

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 info@schuelke.com | www.schuelke.com
 Numeris prekybos registre: Kylio apylinkės teismas, HRB 38 21 NO
 Valdantieji direktoriai: Stefan Kukacka (pirmininkas), Hans-Christian Nehlsen

Banko informacija: Commerzbank AG Frankfurt/Main
 BSC 200 400 00 | Sąskaitos Nr. 42 46 757 00
 SWIFT-BIC: COBA DE FFXXX | IBAN: DE20 2004 0000 0424 6757 00
 PVM mokėtojo kodas: DE 81 2065369
 Kreditoriaus identifikatorius: DE10ZZZ00000006191

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Schülke & Mayr GmbH
Manufacturer address and contact details	Robert-Koch-Str. 2 22851 Norderstedt Germany
Single Registration Number (SRN)	DE-MF-000005701

Notified body name	DQS Medizinprodukte GmbH
Notified body number	0297
Directive Certificate number to which this confirmation is made	004567 MR2
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	18.12.2023
End date of extended validity/transition period	31.12.2028

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the listed **devices** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

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 Trade register number: District court Kiel, HRB 38 21 NO
 Managing Directors: Stefan Kukacka (Chairman), Hans-Christian Nehlsen

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 VAT Reg.No.: DE 81 2065369
 Creditor Identifier: DE10ZZZ000000006191

namely by fulfilling the following conditions:

- **Directive Certificate** as listed above or in the attached schedule
 - Directive Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.

Expired/expires *after* 20 March 2023:

Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made for the devices listed in the attached schedule and signed written agreements will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- **Quality Management System (QMS)**
 - A notified body has issued a certificate for the MDR-compliant QMS.
- **Devices as listed in the attached schedule**
 - The devices continue to comply with MDD.
 - There are no significant changes in the design and intended purpose.
 - The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Schülke & Mayr GmbH

Norderstedt 09.11.2023

i.V. Dr. Susanne Hendrich

Senior Head of Regulatory Affairs

Schülke & Mayr GmbH

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the devices (e.g., device name, family/group name, device model or catalogue number)	Directive Certificate number to which this confirmation is made	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period	Substitute Device(s)
thermosept® ED	004567 MR2	18.12.2023	DQS Medizinprodukte GmbH 0297	DQS Medizinprodukte GmbH 0297	31.12.2028	n/a
gigasept® FF new / Desimatic ID plus	004567 MR2	18.12.2023	DQS Medizinprodukte GmbH 0297	DQS Medizinprodukte GmbH 0297	31.12.2028	n/a
rotasept®	004567 MR2	18.12.2023	DQS Medizinprodukte GmbH 0297	DQS Medizinprodukte GmbH 0297	31.12.2028	n/a

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 VAT Reg.No.: DE 81 2065369
 Creditor Identifier: DE10ZZZ00000006191

DECLARACIÓN CE DE CONFORMIDAD
EC DECLARATION OF CONFORMITY

El Fabricante/Manufacturer: VESISMIN, S.L.U.

Dirección/Address: C/Aribau 230-240, 6th floor, L-O 08006 Barcelona – España

Que fabrica en las instalaciones de/Manufacturing address:

LABORATORIOS ENTEMA, S.L.. Dirección: Pasaje Llobregat, Naves 6-8, Pol. Ind. Can Cortés Sud.
08184 Palau Solità i Plegamans, Barcelona – España

PROERSA, en C/Ricardo de la Cierva, 9-11, Pol. Ind. Sesrovires. 08635 Sant Esteve Sesrovires,
Barcelona - España

DECLARA BAJO SU ÚNICA RESPONSABILIDAD QUE EL PRODUCTO:

/DECLARE UNDER THEIR SOLE RESPONSABILITY THAT THE PRODUCT:

Nombre/Name: NDP Air Total+ GLP CE/*NDP Air total+ GLP CE*

Tipo/Type: IIa

Finalidad prevista/Intended use: Desinfectante de superficies de productos sanitarios no
invasivos/*Disinfectant for surfaces of non-invasive medical devices*

Clasificación (regla)/Classification (rule): 15

CUMPLE LOS REQUISITOS DE LA DIRECTIVA:

/CONFORMS WITH THE REQUISITES OF THE DIRECTIVE:

Directiva/Directive 93/42/CE Directiva de Productos Sanitarios */Medical Devices Directive*

Modificada por la directiva 2007/47/CE, y su transposición a las legislaciones nacionales (En España:
Real Decreto 1591:2009). Requisitos esenciales establecidos en el anexo I.

*As amended by the Directive 2007/47/EC and transposed into national laws (in Spain: Royal Decree
1591:2009). Essential requirements established in Annex I.*

Ruta evaluación de conformidad/Conformity assessment route: Anexo II/*Annex II*

Organismo Notificado/Notified Body: Kiwa Cermet Italia S.p.A. Via Cadriano, 23 – 40057
Granarolo dell'Emilia (BO) Italia. ON nº 0476. Certificado/*Certificate* nº MED 31348 con validez
hasta/*Valid until* 26/05/2024

Sistema de Calidad/Quality system: ISO 13485:2016 – ISO 9001:2015

LUGAR Y FECHA/LOCATION AND DATE: Barcelona, 09 de Enero de 2023 / *Barcelona, 9th of
January 2023*

Firmado/*signed:*


✓ Victor Valles Inautai
Director General / *General Manager*
Vesismín, S.L.U.