Declaration of Conformity

schülke

EC declaration of conformity

Medical Device name		**octenisept® gel**
Formulation No.		F01
Product group		dressing occlusive, hydrogel
Product Category		05 - Hospital hardware
Intended Purpose		Hydrogel for moistening and protection of acute wounds (such as grazes and cuts) and slight burns (also sunburn).
Risk Class according to Directive 93/42/EEC	**annex**	II b IX
Standards applied		EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH, Regulatory Affairs
Manufacturer according to Directive 93/42/EEC		Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt Germany
Notified Body		DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany Ident.No.: 0297
Conformity Assessment Procedure according to Council Directive 93/42/EEC		Annex II excluding section 4
Issued Certificates		Annex II 93/42/EEC Cert. Reg. No. 004567 MR2
Version		4.0

Schülke & Mayr GmbH herewith declares that the device covered by this declation is in conformity with the Council Directive 93/42/EEC concerning medical devices.

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

Norderstedt 06.05.2019

ppa. Dr. Peter Oltmanns
Director Research & Regulatory Affairs
Schülke & Mayr GmbH

06.05.2019

ppa. Dr. Werner Weltgen
Director Quality and HSE
Schülke & Mayr GmbH

This Declaration is valid until an updated version has been issued, but not longer than 18.12.2023

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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info@schuelke.com | www.schuelke.com
Trade register number: District court Kiel, HRB 38 21 NO
Managing Directors: Stefan Kukacka (Chairman), Hans-Christian Nehlsen

Banking details: Commerzbank AG Frankfurt/ Main
BSC 200 400 00 | Account: 42 46 757 00
SWIFT-BIC: COBA DE FFXXX | IBAN: DE20 2004 0000 0424 6757 00
VAT Reg.No.: DE 81 2065369
Creditor Identifier: DE10ZZZ00000006191

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

Digital unterschrieben von
Dr. Susanne Hendrich
Datum: 2023.11.09
07:25:01 +01'00'

i.V. Dr. Susanne Hendrich

Senior Head of Regulatory Affairs

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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)**
octenisan® md nasal gel	004567 MR2	18.12.2023	DQS Medizinprodukte GmbH 0297	DQS Medizinprodukte GmbH 0297	**31.12.2028**	n/a
octenilin® wound gel	004567 MR2	18.12.2023	DQS Medizinprodukte GmbH 0297	DQS Medizinprodukte GmbH 0297	**31.12.2028**	n/a
octenilin® wound irrigation solution	004567 MR2	18.12.2023	DQS Medizinprodukte GmbH 0297	DQS Medizinprodukte GmbH 0297	**31.12.2028**	n/a
octenisept® gel / octenisept® wound gel	004567 MR2	18.12.2023	DQS Medizinprodukte GmbH 0297	DQS Medizinprodukte GmbH 0297	**31.12.2028**	n/a

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