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) (if available)	DE-MF-000005701

Notified body name	DQS Medizinprodukte GmbH
Notified body number	0297
Directive Certificate number to which this confirmation is made	004567 MR2 x See attached schedule
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	26 May 2024

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 **device** 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,

Schülke & Mayr GmbH
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Phone.: +49 40 52100-0 | Fax: +49 40 52100-318
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Certificate covering the listed device was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.

    The certificate expires *after* 20 March 2023:

    Schülke & Mayr GmbH does not intend to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.
- **Quality Management System (QMS)**

  A notified body has issued a certificate for the MDR-compliant QMS.
- **Device as listed in the attached schedule**
  - The device continues to comply with MDD.
  - There are no significant changes in the design and intended purpose.
  - The device does 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 08.11.2023

Digital unterschrieben von Dr. Susanne Hendrich
Datum: 2023.11.08 06:30:38 +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 device(s) (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) 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)**
gigasept® pearls	004567 MR2	18.12.2023	DQS Medizinprodukte GmbH 0297	n/a	26.05.2024	gigasept® pearls by OEM as manufacturer

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EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

schülke

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Disinfectant for medical devices, wound care products and gel as listed in annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	004567 MR2
Certificate unique ID	170772561
Effective date	2020-11-10
Expiry date	2023-12-18
Frankfurt am Main	2020-11-10

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 004567 MR2
Certificate unique ID: 170772561
Effective date: 2020-11-10

Schülke & Mayr GmbH

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Device	Class
[redacted]	
gigasept® pearls	IIb
[redacted]	

Annex to certificate
Certificate registration No.: 004567 MR2
Certificate unique ID: 170772561
Effective date: 2020-11-10

Schülke & Mayr GmbH

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Device	Class
[redacted]	