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	170742365
Effective date	2020-06-09
Expiry date	2023-12-18
Frankfurt am Main	2020-06-09

DQS Medizinprodukte GmbH

Digitally signed by Dubalari Pavel
Date: 2022.02.04 10:18:51 EET
Reason: MoldSign Signature
Location: Moldova

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: 170742365
Effective date: 2020-06-09

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

Device	Class
acryl-des® Gebrauchslösung	IIa
acryl-des® Desinfektionstücher	IIa
antifect® AF (N)	IIa
antifect® N liquid	IIa
antifect® extra	IIa
aspirmatic®	IIa
boots wound healing gel	IIb
dentavon®	IIa
dentavon® liquid	IIa
Essential+ Wipes	IIa
gigasept® AF	IIb
gigasept® AF forte	IIb
gigasept® FF (neu)	IIb
gigasept® Instru AF	IIb
gigasept® med	IIb
gigasept® pearls	IIb
gigasonic®	IIb
gigazyme® Xtra	IIb
mikrozid® AF liquid	IIa
mikrozid® AF wipes	IIa
mikrozid® alcohol free liquid	IIa
mikrozid® alcohol free wipes jumbo	IIa
mikrozid® liquid	IIa
mikrozid® PAA wipes	IIb
mikrozid® sensitive liquid	IIa
mikrozid® sensitive wipes	IIa
mikrozid® universal liquid	IIa
mikrozid® universal wipes	IIa
mikrozid® wipes	IIa
mucalgin®	IIa
mucadont® IS	IIb
mucapur® CD	IIa
mucocit® T	IIb
octenilin® wound gel	IIb
octenilin® wound irrigation solution	IIb
octenisan® md nasal gel	IIa
octenisept® Gel	IIb
octenisept® wound gel	IIb

Annex to certificate
Certificate registration No.: 004567 MR2
Certificate unique ID: 170742365
Effective date: 2020-06-09

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

Device	Class
perform®	IIa
pursept® AF	IIa
pursept® A Xpress liquid	IIa
pursept® A Xpress wipes	IIa
quartamon® med	IIa
rotasept®	IIb
septinol® SA	IIa
terralin® liquid	IIa
terralin® protect	IIa
thermosept® ED	IIb
thermosept® NDR	IIa
TPH® protect	IIa
SteraClar Daily	IIa
SteraDif Powder	IIa
SteraPex	IIb
SteraPex Rotary	IIb
SteraClens Alcohol Free	IIa
SteraClens	IIa
SteriWipe+ Alcohol Free	IIa
SteriWipe+	IIa
DESIMATIC-ID PLUS	IIb
DESIFOR-ONE multi wipes	IIa
DESIFOR-ONE PROTECT	IIa
B3	IIa

CERTIFICATE

This is to certify that the company

schülke

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:
Development, production and sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.

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

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	004567 MP2016
Certificate unique ID	170774693
Effective date	2021-06-27
Expiry date	2024-06-26
Frankfurt am Main	2021-06-27

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

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

410.90.en Version 1.0

Annex to certificate
Certificate registration No.: 004567 MP2016
Certificate unique ID: 170774693
Effective date: 2021-06-27

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

Location	Scope
Schülke & Mayr GmbH Robert-Koch-Straße 2 22851 Norderstedt Germany	Development, production and sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
Schülke & Mayr AG Sihlfeldstrasse 58 8003 Zürich Switzerland	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
Schülke & Mayr Ges. m. b. H. Seidengasse 9 1070 Wien Austria	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
Schülke France S.A.R.L. 50 boulevard National 92250 La Garenne France	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
Schülke & Mayr UK Ltd. Cygnet House, 1 Jenkin Road, Meadowhall Sheffield, S9 1AT United Kingdom	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
Schülke & Mayr Benelux B.V. Oudeweg 8d 2031 CC Haarlem Netherlands	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
Schulke Polska Sp. z o.o. Eurocentrum Office Complex Budynek Delta al. Jerozolimskie 132 02-305 Warszawa Poland	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.

This annex is only valid in connection with the above-mentioned certificate.

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 698961**

Issued To: **O & M Halyard, Inc.**
9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

In respect of:

The manufacture of Surgical Drapes.

Those aspects of Annex V related to securing and maintaining sterility in the manufacture of sterile surgical gowns, surgical drapes, surgical packs and examination gloves

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2019-02-18** Date: **2019-02-25** Expiry Date: **2024-02-17**

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EC Certificate - Production Quality Assurance

Supplementary Information to CE 698961

Issued To:

O & M Halyard, Inc.
9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

Number	Device Name	Intended Purpose per IFU
Class IIa		
MD 0101	Transurethral Resection (T.U.R.) Drapes & Packs	N/A
Class Is		
MDS7006	Surgical Gowns	N/A
MDS7006	Surgical Drapes	N/A
MDS7006	Surgical Packs	N/A
MDS7006	Examination Gloves	N/A

First Issued: **2019-02-18** Date: **2019-02-25** Expiry Date: **2024-02-17**

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 698961**
Date:	**2019-02-25**
Issued To:	**O & M Halyard, Inc.** **9120 Lockwood Blvd** **Mechanicsville** **Virginia** **23116** **USA**

Subcontractor:	**Service(s) supplied**
Arc Royal Virginia Road Kells Co Meath Ireland	**EU Representative**
GRI Medical & Electronic Technology Co., Ltd 1805 Honggao Road Jiaxing Zhejiang 314031 China	**ETO Sterilization** **Manufacture**
Isomedix Operations, Inc. 1441 Don Haskins Drive El Paso Texas 79936 USA	**ETO Sterilization**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 698961**
Date:	**2019-02-25**
Issued To:	**O & M Halyard, Inc.** **9120 Lockwood Blvd** **Mechanicsville** **Virginia** **23116** **USA**

Subcontractor:	**Service(s) supplied**
La Ada de Acuna S. De. R.L. De C.V. Av. Hidalgo No. 6 Esq., Blvd. Luis Donaldo Colosio Col. Educativa, Nogales Sonora 84093 Mexico	**Manufacture**
Lianyungang Aiyeh Non-Woven Products Co., Ltd No. 9 YunYang Rd. Huangjiuni Export Processing Zone Lianyungang, Jiangsu 222047 China	**Manufacture**
Master & Frank (Pinghu) Ent. Co., Ltd. No. 2000, Xingping II Rd. Pinghu Economic Develompment Zone Zhejiang P.R. China	**Manufacture**

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 698961**
Date:	**2019-02-25**
Issued To:	**O & M Halyard, Inc.** **9120 Lockwood Blvd** **Mechanicsville** **Virginia** **23116** **USA**

Subcontractor:	**Service(s) supplied**
O&M Halyard Honduras S.A. de C.V. Carretera Tegucigalpa Villanueva Cortes Honduras	**Manufacture**
O&M Halyard, Inc. 5405 Windward PKWY Alpharetta Georgia 3004 USA	**Regulatory Compliance**
SAFESKIN MEDICAL & SCIENTIFIC (THAILAND), LTD. 200 moo 8 Kanchanavanich Road Tambol Prik, Amphur Sadao Songkhla, 90120 Thailand	**Manufacture**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 698961**
Date:	**2019-02-25**
Issued To:	**O & M Halyard, Inc.** **9120 Lockwood Blvd** **Mechanicsville** **Virginia** **23116** **USA**

Subcontractor:	**Service(s) supplied**
Sterigenics S. de R. L. de C. V. James Watt No. 22 Parque Industrial Cuamatla Cuautitlan Izcalli Estado de México C.P. 54730 Mexico	**ETO Sterilization**
Sterigenics US, LLC 10821 Withers Cove Park Drive Charlotte North Carolina 28278 USA	**Gamma Irradiation**
Sterigenics US, LLC 1302 Avenue T Grand Prairie Texas 75050 USA	**ETO Sterilization**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 698961**
Date:	**2019-02-25**
Issued To:	**O & M Halyard, Inc.** **9120 Lockwood Blvd** **Mechanicsville** **Virginia** **23116** **USA**

Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 687 S. Wanamaker Avenue Ontario California 91761 USA	**ETO Sterilization**
Sterigenics US, LLC 2971 Olympic Industrial Drive SE Suite 116 Atlanta Georgia 30339 USA	**ETO Sterilization**
Sterigenics US, LLC 2400 Airport Road Santa Teresa New Mexico 88008 USA	**ETO Sterilization**

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By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 698961**
Date:	**2019-02-25**
Issued To:	**O & M Halyard, Inc.** **9120 Lockwood Blvd** **Mechanicsville** **Virginia** **23116** **USA**

Subcontractor:	**Service(s) supplied**
Synergy Health (Thailand) Ltd 700/465 Amata Nakorn Industrial Estate Moo 7, Tambol Donhuaroh Amphur Muang Chonburi 20000 Thailand	**Gamma Sterilization**
Synergy Sterilisation (M) Sdn Bhd Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	**Gamma Sterilization**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 698961**

Date: **2019-02-25**

Issued To: **O & M Halyard, Inc.**
9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

Date	Reference Number	Action
18 February 2019	9643055	First Issue.
Current	9643448	Traceable to NB 0086.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

O & M Halyard, Inc.
9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

Holds Certificate No: **FM 697013**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design and development, manufacture and distribution of surgical gowns, protective garments, face masks, surgical drapes, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Packs, orthopedic packs, sterile and non-sterile examination gloves, Temperature management systems for the areas of general surgery and general medical use and sterilization wrap and non-woven materials for medical devices.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2014-12-09
Latest Revision Date: 2020-01-08

Effective Date: 2020-01-09
Expiry Date: 2023-01-08

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Certificate No: **FM 697013**

Location	Registered Activities
O & M Halyard, Inc. 9120 Lockwood Blvd Mechanicsville Virginia 23116 USA	Headquarter management activities.
O & M Halyard, Inc. 5405 Windward Parkway Alpharetta Georgia 30004 USA	The design and development of surgical gowns, protective garments, face masks, surgical drapes, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Packs, orthopedic packs, sterile and non-sterile examination gloves, Temperature management systems for the areas of general surgery and general medical use and sterilization wrap and non-woven materials for medical devices.
Halyard North Carolina, LLC 389 Clyde Fitzgerald Rd. Linwood North Carolina 27299 USA	The manufacture of nonwoven materials for medical devices, Sterilization wrap, and infection control products including disposable gowns and linens.
La Ada de Acuna 14 Finegan Road Del Rio Texas 78840 USA	Receiving and Incoming Inspection, Warehouse and Distribution.
O&M Halyard Honduras S.A. de C.V. Carretera Tegucigalpa Villanueva Cortes Honduras	The manufacture and distribution of disposable sterile and non-sterile surgical gowns.
La Ada de Acuna Avenida Hidalgo #16 Parque Industrial San Carlos Nogales Sonora 84092 Mexico	Receiving and incoming inspection. Manufacturer/Conversion of nonwoven materials.

Original Registration Date: 2014-12-09
Effective Date: 2020-01-09
Latest Revision Date: 2020-01-08
Expiry Date: 2023-01-08

Certificate No: **FM 697013**

Location	Registered Activities
La Ada de Acuna Kim. 4.5 Carreterra Presa La Amistad Ciudad De Acuna Coahuila 26220 Mexico	The manufacture of non-sterile face masks (surgical isolation, industrial and respirator), non-surgical gowns, cold therapy products, and sterilization wrap.
La Ada de Acuna S.De. R.L. De C.V AV. Hidalgo #6 Esq., Blvd., Luis Donaldo Colosio, Col. Educativa Nogales Sonora 84093 Mexico	The manufacture of disposable products including sterile and non sterile surgical packs, gowns and components. The manufacture of temperature management systems for areas of general surgery.
Safeskin Medical & Scientific (Thailand) Ltd. 200 Moo 8, Kanchanavanich Road, Tambol Prik, Amphur Sadao, Songkhla 90120 Thailand	The design and development, production and distribution of industrial gloves, sterile and non-sterile examination gloves.

Original Registration Date: 2014-12-09
Effective Date: 2020-01-09
Latest Revision Date: 2020-01-08
Expiry Date: 2023-01-08

Agenția Națională pentru Sănătatea Publică

CERTIFICAT
DE ÎNREGISTRARE DE STAT/AVIZARE SANITARĂ
AL PRODUSULUI BIOCID

Nr. **00182** data/luna/anul **05.03.2021**

Solicitant: For titular **SC"Endo –Chirurgie" SRL**

Adresa juridică: ***str. Meșterul Manole, 9 mun. Chișinău, Republica Moldova***
Nr. de identificare de stat – codul fiscal 1009600033242

În conformitate cu HG nr. 344 din 10.06.20 și în baza ordinului ANSP **nr. 34 din 02.03.2021**
(nr., data/luna/anul)

emis în baza documentației înaintate, s-a decis că următorul produs biocid poate fi fabricat sau **comercializat și utilizat** în Republica Moldova, conform prevederilor legislației în vigoare.

Denumirea comercială a produsului: Desderman®pure gel

1. Date de identificare ale produsului:
1.1 Categoria de produs: **biocid**
- *Grupa principală:* **1**
- *Tip de produs:* **1**

1.2Utilizare: Dezinfectarea igienică și chirurgicală a mâinilor

1.3 Forma de condiționare și ambalare: **Lichid, ambalaj – flacoane/canistre polimer, de 60 ml, 100 ml, 150 ml, 500ml, 1l, 5l.**

1.4 Conținut în substanțe active: Etanol 96%- 78,20%
Propan-2-ol – 10%
bifenil -2 –ol -0,10%

1.5 Categorii de utilizatori: **Profesionali, industrial**

1.6 Informații privind reglementările aplicabile: **HG nr. 344 din 10.06.2020,**

2. Date de identificare ale producătorului:
2.1 Firma: **„SchUlke&Mayr GmbH", Germania**
2.2 Adresa: **22840 Norderstedt, Germania**

Valabilitatea certificatului de înregistrare data/luna/anul **05.03.2028**
Compoziția, parametrii de calitate ai produsului și domeniul de utilizare sunt cei prevăzuți în documentația tehnică, care a stat la baza eliberării prezentului certificat, conform Raportului de evaluare nr. **169** din **25.02.2021**

Orice modificare a datelor de identificare a produsului biocid, duce în mod automat la anularea certificatului de înregistrare.

Director interimar **Vasile GUȘTIUC**

MINISTERUL SĂNĂTĂȚII, MUNCII ȘI PROTECȚIEI SOCIALE AL REPUBLICII MOLDOVA
AGENȚIA NAȚIONALĂ PENTRU SĂNĂTATE PUBLICĂ
IDNO 1018601000021

Agenția Națională pentru Sănătatea Publică

CERTIFICAT
DE ÎNREGISTRARE DE STAT/AVIZARE SANITARĂ AL PRODUSULUI BIOCID

Nr. **00183** data/luna/anul **05.03.2021**

Solicitant: For titular **SC"Endo –Chirurgie" SRL**

Adresa juridică: ***str. Meșterul Manole, 9 mun. Chișinău, Republica Moldova***

Nr. de identificare de stat – codul fiscal 1009600033242

În conformitate cu HG nr. 344 din 10.06.20 și în baza ordinului ANSP **nr. 34 din 02.03.2021**
(nr., data/luna/anul)

emis în baza documentației înaintate, s-a decis că următorul produs biocid poate fi fabricat sau **comercializat și utilizat** în Republica Moldova, conform prevederilor legislației în vigoare.

Denumirea comercială a produsului: Desderman®pure

1. Date de identificare ale produsului:

1.1 Categoria de produs: **biocid**

- *Grupa principală:* **1**
- *Tip de produs:* **1**

1.2Utilizare: Dezinfectarea igienică și chirurgicală a mâinilor

1.3 Forma de condiționare și ambalare: **Lichid, ambalaj – flacoane/canistre polimer, de 60 ml, 100 ml, 150 ml, 500ml, 1l, 5l.**

1.4 Conținut în substanțe active: Etanol 96%- 78,20%
bifenil -2 –ol -0,10%

1.5 Categorii de utilizatori: **Profesionali, industrial**

1.6 Informații privind reglementările aplicabile: **HG nr. 344 din 10.06.2020,**

2. Date de identificare ale producătorului:

2.1 Firma: **„SchUlke&Mayr GmbH", Germania**

2.2 Adresa: **22840 Norderstedt, Germania**

Valabilitatea certificatului de înregistrare data/luna/anul **05.03.2028**

Compoziția, parametrii de calitate ai produsului și domeniul de utilizare sunt cei prevăzuți în documentația tehnică, care a stat la baza eliberării prezentului certificat, conform Raportului de evaluare nr. **170** din **25.02.2021**

Orice modificare a datelor de identificare a produsului biocid, duce în mod automat la anularea certificatului de înregistrare.

Director interimar **Vasile GUȘTIUC**