

EC DECLARATION OF CONFORMITY

Manufacturer:	SERRES Oy
Manufacturer's Address:	Keskustie 23, FI-61850 Kauhajoki as, Finland
Single Registration Number (SRN)	FI-MF-000004504
Risk Class and Rule	Suction bags Class I according to Rule 2 Annex VIII Accessories Class I according to Rule 1 Annex VIII
Applied standards:	<p>EN ISO 13485:2016 Medical devices- Quality management systems- Requirements for regulatory purposes</p> <p>EN ISO 14971:2019 Medical devices – Application of risk management to medical devices</p> <p>EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. Part 1. General requirements</p> <p>IEC 62366-1:2015 Medical devices- Part 1: Application of usability engineering to medical devices</p> <p>In addition, for Suction bags, Pre-gelled bags, Connectors for patient port, Connectors for canisters, Serres suction bag+ suction tube products</p> <p>EN ISO 10079-1:2015 Medical suction equipment- Part 1: Electrically powered suction equipment (ISO 10079-1:2015)</p> <p>EN ISO 10079-3:2014 Medical suction equipment. Part 3: Suction equipment powered from a vacuum or positive pressure gas source (ISO 10079-3:2014)</p> <p>In addition, for Brackets, wall and rail except for 57814, Brackets table and bed, Vacuum shift,</p> <p>EN ISO 19054:2006 Rail systems for supporting medical equipment.</p> <p>SFS-EN ISO 19054:2006/A1:2016: en Rail systems for supporting medical equipment (ISO 19054:2005/Amd 1:2016)</p>

Product name	Product number	Basic UDI-DI
Suction bags	57151, 57157, 57160, 57161, 57163, 57164, 57165, 57167, 57169, 57170, 57171, 57177, 57187 570157, 6001205, 6001225, 570157-2, 570157-3, 570167-0, 570167-2, 570167-3, 570167-5, 570187-0, 570187-2, 570187-3, 570187-5, 57151-2, 57157-2, 57157-3, 57157-32, 57157-9, 57157JP, 57167-0, 57167-2, 57167-3, 57167-32, 57167-5, 57167-9, 57167JP, 57187-0, 57187-2, 57187-3, 57187-32, 57187-5, 57187-9, 57187JP, 57177-6 57557, 57567-0, 57587-0, 57557-9, 57567-9, 57587-9, 57577, 57557-JP, 57567-OJP, 57587-OJP, 570557, 570567-0, 570587-0 Patient connector 57612, 6001222 included in Suction bags INTENDED USE: The Serres suction bag system is used to collect liquids and secretions for disposal from patients during medical procedures. Suction bag is part of the system.	6418685SBS17Q
Suction bag + tube	57157-23181, 6001206, 6001207, 6001208, 6001209, 6001210, 6001211, 6001212 6001213, 6001214, 6001215, 6001216, 6001217, 6001218, 57157-23185, 57157-23188, 57157-26308, 57167-23181, 57167-23185, 57167-23188, 57167-26301, 57167-26305, 57167-26308, 57187-23181, 57187-23188, 57187-26301 Patient connector 57612, 6001222 included in Suction bag + tube INTENDED USE: The Serres suction bag system is used to collect liquids and secretions for disposal from patients during medical procedures. Suction bag and tube is part of the system.	6418685SBS222S

<p>Smoke filter</p>	<p>57710, 570710, 577109</p> <p>INTENDED USE: Smoke filter does not have a medical purpose. It is intended for use as an accessory to the Suction Bag System.</p> <p>Smoke filter is used to prevent premature blockage of the suction bag overflow protection during surgical operations when very heavy smoke is generated.</p>	<p>6418685SBS202N</p>
<p>Vacuum source protector</p>	<p>6001114, 6006552</p> <p>INTENDED USE: Vacuum source protector does not have a medical purpose. It is intended for use as an accessory to the Suction Bag System.</p> <p>The protector is used to prevent liquid entering the vacuum source in case of an installation error of a suction bag.</p>	<p>6418685SBS212Q</p>
<p>Serial tubing</p>	<p>57918, 570918, 57918-9</p> <p>INTENDED USE: Serial tubing does not have a medical purpose. It is intended for use as an accessory to the Suction Bag System.</p> <p>Serial tubing is used to connect Serres suction bags in series when large volume of liquids is collected.</p>	<p>6418685SBS57Y</p>
<p>Twin Connector</p>	<p>57620, 57620-9, 570620</p> <p>INTENDED USE: Twin Connector does not have a medical purpose. It is intended for use as an accessory to the Suction Bag System.</p> <p>Twin Connector is designed to replace the suction bag's patient connector if simultaneous suction from two sites is needed.</p>	<p>6418685SBS232U</p>

Straight Connector	57621, 570621, 576219, INTENDED USE: Straight Connector does not have a medical purpose. It is intended for use as an accessory to the Suction Bag System. Straight Connector is used as replacement for the patient connector if a suction tube with a large diameter is used.	6418685SBS242W
T-connector	57610, 576109, 570610 INTENDED USE: T-Connector does not have a medical purpose. It is intended for use as an accessory to the Suction Bag System. T-connector is used in serial connections and can replace the Serres valve when the smoke filter is used.	6418685SBS37U
Vacuum tubing	57908, 570908, 57908-9 INTENDED USE: Vacuum tubing does not have a medical purpose. It is intended for use as an accessory to the Suction Bag System. Vacuum tubing is used in serial connection to share the vacuum between canisters.	6418685SBS47W
Vacuum tube roll	57899, 570899, 57899-9 INTENDED USE: Vacuum tube roll does not have a medical purpose. It is intended for use as an accessory to the Suction Bag System. Vacuum tube roll is used to connect suction bag system to vacuum source.	6418685SBS252Y

<p>Rail Brackets</p>	<p>57815, 570815, 57815-0, 57815-9, 57818, 570818</p> <p>INTENDED USE: Rail brackets do not have a medical purpose. They are intended for use as an accessory to the Suction Bag System.</p> <p>Rail Brackets are used to hold Serres suction canister in upright position when mounted on hospital rails.</p>	<p>6418685SBS122P</p>
<p>Wall Brackets</p>	<p>57820, 570820, 57820-9, 57814, 570814, 57817, 570817</p> <p>INTENDED USE: Wall brackets do not have a medical purpose. They are intended for use as an accessory to the Suction Bag System.</p> <p>Wall Brackets are used to hold Serres suction canister in upright position when mounted on wall.</p>	<p>6418685SBS132R</p>
<p>Bed Brackets</p>	<p>57830, 570830, 57830-9</p> <p>INTENDED USE: Bed bracket does not have a medical purpose. It is intended for use as an accessory to the Suction Bag System.</p> <p>Bed bracket is used to hold Serres suction canister in upright position when mounted on hospital beds.</p>	<p>6418685SBS2632</p>
<p>Table Brackets, Table stand</p>	<p>57825, 570825, 57825-9, 57835, 57836, 570835, 570836</p> <p>INTENDED USE: Table stands do not have a medical purpose. They are intended for use as an accessory to the Suction Bag System.</p> <p>Table Stands and bracket are used to hold Serres suction canister in upright position when mounted on table surface.</p>	<p>6418685SBS2734</p>

Vacuum shift	57955, 570955, 57955-9 INTENDED USE: Vacuum Shift does not have a medical purpose. It is intended for use as an accessory to the Suction Bag System. Vacuum Shift is designed for shifting vacuum between two suction lines. It is assembled into the Serres bracket. Vacuum Shift has four functions: suction shut-off, two lines open, or one line open at a time.	6418685SBS784
Serres Valve	57958, 570958, 57958-9 INTENDED USE: Serres Valve does not have a medical purpose. It is intended for use as an accessory to the Suction Bag System. The Serres valve is used to open and shut off suction in connection to using a smoke filter.	6418685SBS682
On-Off Valve	57959, 57959-9, 570959 INTENDED USE: On-Off Valve or T-Valve does not have a medical purpose. They are intended for use as an accessory to the Suction Bag System. The On-Off valve is used to open and shut off suction. It is installed to the control valve or it may be installed in the suction canister connection to replace the angle connector.	6418685SBS2836
T-Valve	6004914 INTENDED USE: On-Off Valve or T-Valve does not have a medical purpose. They are intended for use as an accessory to the Suction Bag System. The T-Valve is used to open and shut off suction in serial connection. It is installed to the suction canister to replace the T-connector.	6418685SBS2938

<p>Trolleys and trolley accessories,</p>	<p>57940, 57940-9, 570940, 57945, 57945-9, 570945 6003199, 6001301</p> <p>INTENDED USE: Trolleys do not have a medical purpose. They are intended for use as an accessory to the Suction Bag System.</p> <p>Trolleys are used to hold Serres suction canisters and accessories during the procedures.</p>	<p>6418685SBS112M</p>
<p>Canister holder</p>	<p>57941, 570941, 6001263</p> <p>INTENDED USE: Canister holder is used to hold canisters in upright position or to expand the capacity of the trolley.</p>	<p>6418685SBS302R</p>
<p>Control valve</p>	<p>57942, 570942</p> <p>INTENDED USE: Control valve facilitates speedy individual use of a Serres suction bag. Serres Control Valve is installed inside the canister holder of a Serres High Trolley.</p>	<p>6418685SBS312T</p>
<p>Control valve plug</p>	<p>57943, 570943</p> <p>INTENDED USE: Control valve plugs are used to seal the unused connections of the control valve.</p>	<p>6418685SBS322V</p>
<p>Serres Tip Adapter</p>	<p>58280-1, 6001219</p> <p>INTENDED USE: Vacuum control adapters do not have a medical purpose. They are intended for use as an accessory to the Suction Bag System.</p> <p>Serres Tip Adapter is connected between the suction catheter and the patient tube to adjust vacuum strength.</p>	<p>6418685SBS332X</p>

<p>Stop Vacuum</p>	<p>58250, 58260, 6001220, 6001221</p> <p>INTENDED USE: Vacuum control adapters do not have a medical purpose. They are intended for use as an accessory to the Suction Bag System.</p> <p>Stop Vacuum is connected between the suction catheter and the patient tube to open/close vacuum.</p>	<p>6418685SBS886</p>
<p>Collection cup</p>	<p>57242, 57247, 570247, 572429, 57247-9</p> <p>INTENDED USE: Collection Cup does not have a medical purpose. It is intended for use as an accessory to the Suction Bag System.</p> <p>Collection Cup is used to collect particles from the suctioned liquid into the basket of the cup.</p>	<p>6418685SBS988</p>
<p>Collection Pouch Valve</p>	<p>6004479</p> <p>INTENDED USE: Collection Pouch Valve is intended for use as an accessory to Serres Saga Fluid management system and to Serres Suction Bag System.</p> <p>Collection Pouch Valve is used to prevent suction loss in operations where collection pouch is in use.</p>	<p>6418685SAGA92F</p>

This Declaration of Conformity is issued under the sole responsibility of Serres Oy.
 We hereby declare that the medical devices specified above meet the provision of the EU Regulation 2017/745 for medical devices.

Kauhajoki 3rd of February 2022

Serres Oy



Nicke Svanvik

CEO



DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 203225-2016-CE-FIN 0.0

This Certificate consists of 3 pages

This is to certify that the Quality Management System of

SERRES OY

Keskustie 23, FI-61850 Kauhajoki as, Finland

for design, production and final product inspection/testing of

Secretion collection system

has been assessed with respect to

the conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:

Høvik, 30 June 2016

This Certificate is valid until:

08 June 2020

For DNV GL BUSINESS ASSURANCE
NORWAY AS



Tone Kolpus



Tone Kolpus
Certification Manager

Notified Body No.:
0434

Aud Løken Eiklid
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300.000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.



Cert. No.: 203225-2016-CE-FIN
Rev. No.: 0.0
Project No.: PRJC-548210-2016-MSF-FIN

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

Certificate history

Revision	Description	Issue Date
0	Original certificate	2016-06-30

Products covered by this Certificate

Product Description	Product	Class
Secretion collection system	Suction Canisters and Measuring Cup	Im
Secretion collection system	Q-VAC Ejector	IIa

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate

Keskustie 23, FI-61850 Kauhajoki as, Finland



Cert. No.: 203225-2016-CE-FIN
Rev. No.: 0.0
Project No.: PRJC-548210-2016-MS-C-FIN

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the local DNV Office of any intended updating of the quality system and DNV will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system DNV reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of DNV.

END OF CERTIFICATE