

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	Class I
Applied standards:	<p>EN ISO 13485:2016 Medical devices- Quality management systems- Requirements for regulatory purposes</p> <p>EN ISO 14971:2012 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>EN 1041:2008 + A1:2013 Information supplied by the manufacturer of medical devices.</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	<p>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</p> <p>57557, 57567-0, 57587-0, 57557-9, 57567-9, 57587-9, 57577, 57557-JP, 57567-OJP, 57587-OJP, 570557, 570567-0, 570587-0</p> <p>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.</p>	<p>06418685SBS1NR</p>
Suction bag + tube	<p>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</p> <p>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.</p>	<p>06418685SBS22KF</p>

Smoke filter	57710, 570710, 577109 INTENDED USE: Smoke filter does not have a medical purpose. It is intended for use as an accessory to the Suction Bag System. Smoke filter is used to prevent premature blockage of the suction bag overflow protection during surgical operations when very heavy smoke is generated.	06418685SBS20KB
Vacuum source protector	6001114 INTENDED USE: Vacuum source protector does not have a medical purpose. It is intended for use as an accessory to the Suction Bag System. The protector is used to prevent liquid entering the vacuum source in case of an installation error of a suction bag.	06418685SBS21KD
Serial tubing	57918, 570918, 57918-9 INTENDED USE: Serial tubing does not have a medical purpose. It is intended for use as an accessory to the Suction Bag System. Serial tubing is used to connect Serres suction bags in series when large volume of liquids is collected.	06418685SBS5NZ
Twin Connector	57620, 57620-9, 570620 INTENDED USE: Twin Connector does not have a medical purpose. It is intended for use as an accessory to the Suction Bag System. Twin Connector is designed to replace the suction bag's patient connector if simultaneous suction from two sites is needed.	06418685SBS23KH

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.	06418685SBS24KK
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.	06418685SBS3NV
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.	06418685SBS4NX
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.	06418685SBS25KM

<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>06418685SBS12KC</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>06418685SBS13KE</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>06418685SBS26KP</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>06418685SBS27KR</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.	06418685SBS7P5
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.	06418685SBS6P3
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.	06418685SBS28KT
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.	06418685SBS29KV

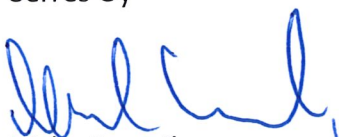
Trolleys and trolley accessories,	57940, 57940-9, 570940, 57945, 57945-9, 570945 6003199, 6001301 INTENDED USE: Trolleys do not have a medical purpose. They are intended for use as an accessory to the Suction Bag System. Trolleys are used to hold Serres suction canisters and accessories during the procedures.	06418685SBS11KA
Canister holder	57941, 570941, 6001263 INTENDED USE: Canister holder is used to hold canisters in upright position or to expand the capacity of the trolley.	06418685SBS30KE
Control valve	57942, 570942 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.	06418685SBS31KG
Control valve plug	57943, 570943 INTENDED USE: Control valve plugs are used to seal the unused connections of the control valve.	06418685SBS32KJ
Serres Tip Adapter	58280-1, 6001219 INTENDED USE: Vacuum control adapters do not have a medical purpose. They are intended for use as an accessory to the Suction Bag System. Serres Tip Adapter is connected between the suction catheter and the patient tube to adjust vacuum strength.	06418685SBS33KL

<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>06418685SBS8P7</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>06418685SBS9P9</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 19th of May 2021

Serres Oy



Nicke Svanvik
 CEO