

## EC DECLARATION OF CONFORMITY

<b>Manufacturer:</b>	<b>SERRES Oy</b>
<b>Manufacturer's Address:</b>	Keskustie 23, FI-61850 Kauhajoki as, Finland
<b>Single Registration Number (SRN)</b>	FI-MF-000004504
<b>Risk Class and Rule</b>	Suction bags Class I according to Rule 2 Annex VIII Accessories Class I according to Rule 1 Annex VIII
<b>Applied standards:</b>	<p><b>EN ISO 13485:2016</b> Medical devices- Quality management systems- Requirements for regulatory purposes</p> <p><b>EN ISO 14971:2019</b> Medical devices – Application of risk management to medical devices</p> <p><b>EN ISO 15223-1:2016</b> Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. Part 1. General requirements</p> <p><b>IEC 62366-1:2015</b> 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><b>EN ISO 10079-1:2015</b> Medical suction equipment- Part 1: Electrically powered suction equipment (ISO 10079-1:2015)</p> <p><b>EN ISO 10079-3:2014</b> 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><b>EN ISO 19054:2006</b> Rail systems for supporting medical equipment.</p> <p><b>SFS-EN ISO 19054:2006/A1:2016:</b> en Rail systems for supporting medical equipment (ISO 19054:2005/Amd 1:2016)</p>

Product name	Product number	Basic UDI-DI
<b>Suction bags</b>	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
<b>Suction bag + tube</b>	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><b>Smoke filter</b></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><b>Vacuum source protector</b></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><b>Serial tubing</b></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><b>Twin Connector</b></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>

<b>Straight Connector</b>	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
<b>T-connector</b>	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
<b>Vacuum tubing</b>	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
<b>Vacuum tube roll</b>	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

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

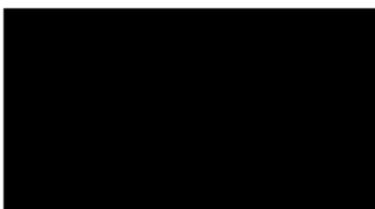
<b>Vacuum shift</b>	57955, 570955, 57955-9  INTENDED USE: Vacuum Shift does not have a medical purpose. It is intended for use as an accessory to the Suction Bag System.  Vacuum Shift is designed for shifting vacuum between two suction lines. It is assembled into the Serres bracket. Vacuum Shift has four functions: suction shut-off, two lines open, or one line open at a time.	6418685SBS784
<b>Serres Valve</b>	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
<b>On-Off Valve</b>	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
<b>T-Valve</b>	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><b>Trolleys and trolley accessories,</b></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><b>Canister holder</b></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><b>Control valve</b></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><b>Control valve plug</b></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><b>Serres Tip Adapter</b></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><b>Stop Vacuum</b></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><b>Collection cup</b></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><b>Collection Pouch Valve</b></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



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