

## **Declaration of Conformity EU**

Document ID: Created by: Approved by: Approval date: PD-511386 Rev: 07 Zahrah Chaudhary Karin Darle Olsson 2019-02-18

Title: Trocars Page 1(3)

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being exclusively responsible manufacturer for conformity of the device/s; declare that the devices listed in the attached schedule are in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade name/
Product name:

Trocars

Product classification: Ila

Sterility Status: Sterile

Measuring function: No

This declaration is supported by a conformity assessment procedure in accordance with

Annex/es:

Certificate number: CE 01965

Issued by: **BSI (0086)** 

For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: 2019-02-18 Function: Regulatory Affairs Manager

Compliance

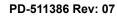
Name: Karin Darle Olsson Signature:



Title: Trocars Page 2(3)

## Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
899300	Shielded Bladed Trocar 5mm / 70mm	42412
899301	Shielded Bladed Trocar 5mm / 100mm	42412
899302	Shielded Bladed Trocar 11mm / 100mm	42412
899303	Shielded Bladed Trocar 11mm / 150mm	42412
899304	Shielded Bladed Trocar 12mm / 100mm	42412
899305	Shielded Bladed Trocar 12mm / 150mm	42412
899306	Hasson Trocar 11mm / 100mm	42412
899307	Hasson Trocar 12mm / 100mm	42412
899308	Bladeless Dilating Tip Trocar 5mm / 70mm	42412
899309	Bladeless Dilating Tip Trocar 5mm / 100mm	42412
899310	Bladeless Dilating Tip Trocar 11mm / 100mm	42412
899311	Bladeless Dilating Tip Trocar 11mm / 150mm	42412
899312	Bladeless Dilating Tip Trocar 12mm / 100mm	42412
899313	Bladeless Dilating Tip Trocar 12mm / 150mm	42412
899314	Optical Trocar 11mm / 100mm - Pistol Grip	42412
899315	Optical Trocar 12mm / 100mm - Pistol Grip	42412
899316	Optical Trocar 5mm / 70mm	42412
899317	Optical Trocar 5mm / 100mm	42412
899318	Optical Trocar 11mm / 100mm	42412
899319	Optical Trocar 12mm / 100mm	42412





Title: Trocars Page 3(3)

Product Reference:	Product Descriptor:	GMDN Code:
899320	Universal Trocar Cannula 5mm / 70mm	42412
899321	Universal Trocar Cannula 5mm / 100mm	42412
899322	Universal Trocar Cannula 11mm / 100mm	42412
899323	Universal Trocar Cannula 12mm / 100mm	42412
899324	Optical Trocar 5mm / 150mm	42412
899325	Optical Trocar 11mm / 150mm	42412
899326	Optical Trocar 12mm / 150mm	42412
899327	Optical Balloon Trocar 5mm / 100mm	42412
899328	Optical Balloon Trocar 12mm / 100mm	42412
899329	Hasson Balloon Trocar 12mm / 100mm	42412
899330	Optical Balloon Trocar 5mm / 70mm	42412
899331	Optical Balloon Trocar 11mm / 100mm	42412
899336	Bladeless Dilating Tip Trocar 15mm / 100mm	42412