

We, Mölnlycke Health Care AB, Gamlestadvägen 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
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Product classification: **IIa**

Sterility Status: **Sterile**

Measuring function: **No**

This declaration is supported by a conformity assessment procedure in accordance with Annex/es: II	
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Certificate number:	CE 01965
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Issued by:	BSI (0086)
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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:



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

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