

TEHNOMEDICA

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Către IMSP Institutul de Cardiologie

În atenția Grupului de lucru
al Licitației nr. ocds-b3wdp1-MD-1569830222901

ID: 21012662 din 28.10.2019

Articole parafarmaceutice, consumabile și obiecte de mică valoare

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, declarăm că, produsele oferite în cadrul licitației prenotate, au fost livrate pe parcursul anului 2019 (conform contractului nr.3682-15 din 18.02.2019), iar la necesitate, vom prezenta mostre în decurs de 3 zile de la solicitarea autorității contractante.

Cu respect,

Director
28.10.19



Tatiana Roibu

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 01966**
Issued To: **Mölnlycke Health Care AB**
Box 13080
Gamlestadsvägen 3C
SE-402 52 Göteborg
Sweden

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **1998-06-29**

Date: **2018-05-30**

Expiry Date: **2023-06-28**

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
 This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
 A member of BSI Group of Companies.



Certificate No: CE 01966

Certificate Scope:

Those aspects of manufacture related to securing and maintaining sterility of absorbent tracheostomy dressing, sterile scar management dressing and transparent adhesive IV film dressing.

Those aspects of manufacture related to securing and maintaining sterility of negative pressure wound therapy (NPWT) accessories, surgical and equipment drapes and surgical gowns.

Those aspects of manufacturing relating to securing and maintaining sterility in the assembly of procedure packs in accordance with article 12 of the MDD.

First Issued: **1998-06-29**

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Page 2 of 2

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