

**INTERSTER** 

Statement

**Manufacturer:** Interster International  
Samsonweg 2a  
1521 RC Wormerveer

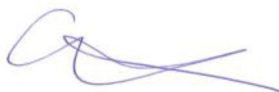
**Product:** ISP® Bowie&Dick A4-size Test Sheets  
ISP® Bowie&Dick Autoclave Testpacks  
ISP® Helix Test Systems  
ISP® Steam Emulating Indicators  
ISP® Dual Steam Emulating Indicator  
ISP® Steam Monitoring Strips  
ISP® Dual Steam Monitoring Strips  
ISP® Instru Protectors  
ISP® Formaldehyde Indicators  
ISP® Registration Cards  
ISP® Documentation Envelopes  
Interster Seal Checks

We herewith declare that above products from this statement are latex-free and DEHP-free ,Di(2-EthylHexyle) Phthalate.

**Standard applied:** ISO 9001:2008  
ISO 13485:2003

**Place, date of Issue** Wormerveer, 19-08-2010

**Signature:**



Name: S. Kool  
Position: Quality Manager a.i

**TRADUZIONE  
DICHIARAZIONE**

**PRODUTTORE:** INTERSTER INTERNATIONAL BV  
Samsonweg 2a  
1521 RC Wormerveer (NL)

**PRODOTTI:** ISP® Bowie&Dick A4 foglio indicatore  
ISP® Bowie&Dick Autoclave test pack  
ISP® Helix Test System  
ISP® Steam Emulating Indicators  
ISP® Steam Monitoring Strips  
ISP® Dual Steam Monitoring Strips  
ISP® Instru Protector  
ISP® Formaldehyde Indicator  
ISP® Registration Cards  
ISP® Documentation Envelopes  
ISP® Seal Check

Si dichiara con la presente che i sopra elencati prodotti sono privi di lattice e DEHP (di-2-etilossiftalato) ftalati.

Norme applicate: EN ISO 9001: 2008  
EN ISO 13485: 2003

**Dichiarazione contenuto lattice e DEHP**

**INTERSTER** 

**Declaration of Conformity  
Helix Test System**

**Manufacturer:** Interster International Sterilisatie & Steriliteit B.V.  
Samsonweg 2a  
1521 RC Wormerveer  
Netherlands

**Product family:** Helix Test System Products

**Product number / name:** 3FSKS630850 (I3002030) ISP® Helix Test System 3,5 min.

We herewith declare that the above mentioned product applies to the EN-ISO-11140-1:2009 Class 2 + 6 indicators, the EN 867-5:2001(paragraph 4.5.7). All supporting documentation is retained under permission of manufacturer.

**Standard applied:** ISO 9001:2008  
ISO 13485:2003  
EN 867-5:2001(paragraf 4.5.7)  
EN-ISO-11140-1(Class 2 + 6):2009

**Place, date of issue:** Wormerveer, 04-02-2014

**Signature:**



Name: B. Randshuizen  
Position: Quality Manager

1/1

**Dichiarazione di Conformità**

**TRADUZIONE**

**Produttore:** Interster International  
Samsonweg 2A  
1521 RC Wormerveer

**Famiglia prodotto:** Helix Test System

**Codice prodotto:** 3FSKS630850 (I3002030) ISP® Helix Test System 3,5 min

Si dichiara con la presente che il sopra indicato prodotto è in conformità con le disposizioni delle norme EN ISO 11140-1: 2009 (indicatore di Classe 2 e 6) e della EN 867-5: 2001 (paragrafo 4.5.7). Tutta la documentazione di supporto è conservata presso la sede del produttore.

**Norme applicate:** ISO 9001: 2008  
ISO 13485: 2003  
EN 867-5: 2001 (paragrafo 4.5.7).  
EN ISO 11140-1: 2009 (Indicatore di Classe 2 e 6)

bsi.



**BSI Group Deutschland GmbH**  
Eastgate, Hanauer Landstrasse 115  
60314 Frankfurt am Main  
Germany

herewith confirms, that the company

**INTERSTER**

**Interster International**  
Samsonweg 2a  
1521 RC Wormerveer  
Netherlands

has established a **quality management system** for the

Design and development, manufacturing and distribution of custom procedure trays, sterile systems, gowns and drapes, sterilisation control products, packaging materials for central sterilisation departments and logistic devices and -concepts.

Design, development and provision of education to medical professionals on prevention and control of infection.

An audit has provided evidence that the quality system is in compliance with the requirements of

**DIN EN ISO 9001 : 2008.**

Report No.: SMO8109603  
**Certificate No.: FM 610234**

Current Issue Date: March 16, 2014

**bsi.**  
Certification Body

Certificate



First Issue Date:  
March 16, 2014

Based on annual surveillance  
this certificate is valid until  
April 01, 2015.



**BSI Group Deutschland GmbH**  
Eastgate, Hanauer Landstrasse 115  
60314 Frankfurt am Main  
Germany

herewith confirms, that the company

**INTERSTER**

**Interster International**  
Samsonweg 2a  
1521 RC Wormerveer  
Netherlands

has established a **quality management system** for the

Design and development, manufacturing and distribution of custom procedure trays, sterile systems, gowns and drapes, sterilisation control products and packaging materials for central sterilisation departments.

An audit has provided evidence that the quality system is in compliance with the requirements of

**DIN EN ISO 13485 : 2012**  
**(EN ISO 13485 : 2012 + AC : 2012).**

Report No.: SMO8109606  
**Certificate No.: MD 610235**

Current Issue Date: March 16, 2014

**bsi.**  
Certification Body

Certificate



First Issue Date:  
March 16, 2014

Based on periodical surveillance  
this certificate is valid until  
April 01, 2015.

Certificazioni ISO 9001 : 2008 e ISO 13485 : 2012