

Statement Helix Test Systems

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

Client: DeRaimas Joint Stock Company
Sausio 15-Osios g.7
Lt-91228 Klaipėda
Lithuania

Product family: Control Products

Product group: ISP® Helix Test Systems

Product number / name: 3FSKS630802 INT ISP Helix Test System 3,5 min.(100pcs)
3FSKS630804 INT ISP Helix Test System 3,5 min.(400pcs)
3FSKS630806 INT ISP Helix Test System 5,3 min.
3FSKS630808 INT ISP Helix Test System 7,0 min.

We herewith declare that the above mentioned products, can be used to monitor sterilization conditions in B type sterilization cycles for any loads configurations (solid, porous, simple hollow or narrow lumen devices mixed load or only), as single or double wrapped in to eligible packaging or unwrapped. The above mentioned products also function as a device to monitor the removal of air and the penetration of steam, similar to a Bowie & Dick Type Test Pack.

Standard & regulations

Applied: Directive 93/42/EEC for medical devices as amended by
2007/47/EC for medical devices

ISO 9001:2008

ISO 13485:2012

ISO 11140-1:2014 (Type 2)

Place, date of Issue: Wormerveer, 04-03-2015

Signature:



Name: Bob Randshuizen
Position: Quality Manager