

EU Declaration of Conformity

This EU declaration of conformity is issued under the sole responsibility of the manufacturer, importer & distributor –

Joerns Healthcare Limited, Drakes Broughton Business Park, Worcester Road, Pershore, Worcestershire, UK. WR10 2AG.

The device that is covered by the present declaration is in conformity with EC Council Directive for Medical Devices 93/42/EEC of 14 June 1993 & Medical Device Regulation (EU) 2017/745.

Product Name: Oxford Professional Calibre

Description: The Oxford Professional Calibre range of hoists are ergonomically designed mobile devices for the safe lifting and handling of patients for the transfer or moving a person over short distances.

Product Codes: OXF-CALIBRE-S

Actor ID/SRN: GB-MF-000013472

Basic UDI-DI (GMN): 50556184OXF-PROSD **GMDN:** 12330

Classification Type: Class I [Rule 1 of MDR 2017/745, Annex VIII, Chapter III, Section 4.1]

Authorised Representative: Joerns Healthcare BV, Zeilschip 26,3991 CT Houten, Netherlands

This device was tested and is in conformity with all relevant clauses within the following standards:

| Standard | Description |
|----------------------|---|
| BS EN ISO 10535:2006 | Hoists for the transfer of disabled persons |
| BS EN ISO 12182:2012 | Assistive products for persons with disability. General requirements & test methods |
| BS EN ISO 14971:2019 | Application of Risk Management to medical devices |

Issued By: Stan Snijders – Managing Director of Joerns Healthcare, Europe

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Location: UK / Netherlands

On behalf of: Joerns Healthcare Limited, UK

Signature: 