

Declaration of Conformity (Certificate Ref. JH014 Rev. C)

This 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 Medical Device Regulation (EU) 2017/745.

Product Name: Oxford Switch

Description: The Oxford Switch is a sit-to-stand and transfer device for moving a person over short distances. This might be bed to chair, chair to wheelchair or to and from a toilet/commode, for example.

Product Code: OXF-SWITCH

Actor ID/SRN: GB-MF-000013472 (UK Rep) NL-AR-000006632 (NL Rep)

Basic UDI-DI (GMN): 50556184OXF-PROSD **GMDN:** 46148 **EMDN:** V0805

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 10535:2021 | Hoists for the transfer of disabled persons |
| BS EN ISO 12182:2012 | Assistive products for persons with disabilities. General requirements & test methods |
| BS EN ISO 14971:2019 | Application of Risk Management to medical devices |
| BS EN ISO 13485:2016 | Regulatory requirements for medical device quality management systems |

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

Issue Date: 01/11/2023

Location: UK / Netherlands

On behalf of: Joerns Healthcare Limited, UK

Signature: 