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**EU Declaration of Conformity CE Certification MDR 2017/745**

This EU declaration of conformity (DoC) is issued under the sole responsibility of Arden Medical Ltd, the manufacturer of the below listed CE marked medical devices. The requirements specified in EU Regulation 2017.745 (MDR) regarding medical devices have been fulfilled in relation to the listed device groups. The devices are also in conformity with EU Directive 2011/65/EU, as amended by Directive 2015/863 RoHS 3), on the restriction of use of certain substances in electrical and electronic equipment.

Arden Medical Ltd is certified as meeting quality management systems in accordance with standards ISO 13485:2016 and its QA systems are audited by BSI Ltd – UK.

Intended use of flexible splints and their accessories:

Stroke Rehabilitation.

**Urias Non Sterile Rehabilitation Splints:** used for short term periods as an aid to rehabilitation of stroke patients as they inhabit spasticity by controlling tonal patterns and allowing a motor retraining programme to develop.

Listed Models - Splints:

Global Model Number (GMN) Basic UDI-DI ref: 5065006483U702C

Classification: The splints are classified as Class 1 devices

**Accessory – Non Sterile Urias Model Filter Bottle and Mouthpieces,** intended use to dry mouth condensate air used in manual inflation of the splints.

Global Model Number (GMN) Basic UDI-DI ref: 5065006483U752N

Classification: The accessories are classified as Class 1 devices

Therapeutic:

Urias None Sterile Therapeutic Splints listed above can also act as an aid to rehabilitation and management of patients with neurological damage. They may also help to prevent the development of contractures in upper and lower limits and where contractual deformity has already developed. The splints may be used to stretch the contractures and gradually reduce the deformity.

EC	REP
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EC authorised representative: Eucerep B.V., Roald Dahlaan 33, 5629MC, Eindhoven, Netherlands.

Signed:

D.Wade

Managing Director

On behalf of Arden Medical Ltd

Place: Warwickshire B49 6HN, UK

Date 14/01/2021