



Declaration of Conformity

DoC/2017/745/M12938/ADAPTABLESC

The declaration of Conformity has been issued by (manufacturer): Urathon Limited Thane House, Hilmarton, Wiltshire, SN11 8SB

The Declaration of Conformity is in accordance with **Medical Device Regulations 2017/745** and is issued under the sole responsibility of the manufacturer Urathon.

The Devices will be supplied with a basic UDI DI: (01) DI - (10) PI (EAN barcode/GS1) from the resellers

The declaration covers **M12938 Adaptable Ali Shower Chair** whose intended purpose is to support the patient in mobilizing, all devices issued are identifiable by a unique serial no included on UDI-DI as above.

The device risk class in accordance to the MDR 2017/745 (Annex VIII) is class 1 Medical Device, and this declaration confirms the conformity to the regulation has been assessed and complies where applicable.

Common Specifications: The device has been manufactured and tested in accordance with: BS EN ISO 11199-2:2005 Walking aids manipulated by both arms. Requirements and test methods - Part 2: Rollators.

Declaration approved by: Mike Ives

Position: Engineering Manager

On behalf of: Urathon Limited

Signed at: Urathon limited Thane House, Hilmarton, Wiltshire, SN11 8SB

Signature: *Mike Ives*

Date: August 2020