

DECLARATION OF CONFORMITY DoC/2017/745/UEL90529 PU PS

The Declaration of Conformity has been issued by (manufacturer): Urathon Europe 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 (10) PI (EAN barcode/GS1) from the resellers

The declaration covers **UEL-90529 PU Perching Stool (Grey)** whose intended purpose is to support the patient in mobilizing. All devices issued are identifiable by a unique serial

number included on UDI-DI as above.

The device risk class in accordance to the MDR2017/745 (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 21856: 2022 - Assistive Products - General Requirements & Test Methods.

Declaration approved by: Hugh Sims-Hilditch

Position:

Executive Chairman

On behalf of:

Urathon Europe Limited Urathon Europe Limited, Thane House, Hilmarton, Wiltshire, SN11 8SB

Signed at: Signature:

Date: August 27th 2023

EC REP

Ives MD EU Rep Ltd 44 Rosses Stables, Ballymena, Co. Antrim, N.I. BT42 2SF

DoC2017/745/UEL-90674 PU PS PU Perching Stool

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