

DECLARATION OF CONFORMITY



This declaration of conformity is issued under the sole responsibility of Roma Medical Aids Ltd.

Classification: Class 1 Medical Device (EU)

Basic UDI-DI (GMN): 5055721234936WB

GMDN Code: 34936 – Shower seat, non-powered

Intended Use: A non-powered device designed to be sat upon by a patient (adult or child) while washing in a shower, or other washing facility (e.g., bath). The patient is typically disabled, infirm, or is undergoing medical treatment and requires to be seated while bathing/showering. The device may be in the form of a portable chair/stool or a fixed seat (e.g., wall-mounted), and may include armrests, side supports, or grab handles; it is typically made of water-resistant or waterproof materials (e.g., plastic and metal-coated materials). It may be used in a hospital, institution, or home.

Catalogue/Reference (REF) of included products:

4145G	4216F/NS	4278	4550/HD/4BC
4146G/4BC	4216P	4278D	4550/HD/DA/4BC
4160	4221	4279	4551/4BC
4204	4222A	4279D	4553
4207A	4225	4544B/4BC	4553/HD
4207B	4258	4550/4BC	4553EX
4208	4261G	4550/4BC/FR	4557
4216			

Manufacturer:

Roma Medical Aids Ltd.
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Bridgend Industrial Estate
Bridgend
CF31 3TB

Company Registration No. 1869285

SRN: GB-MF-000013502

Authorised EU Representative:

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Westplein 12-14
3016 BM
Rotterdam
The Netherlands

Company Registration No. 24379448

SRN: NL-AR-000012537

Standards: EN ISO 9001, EN ISO 13485

Roma Medical Aids Ltd declares that the above-mentioned product(s) conform to the requirements specified in the Medical Devices Regulation (EU) 2017/745.



Signed by:

R Pitt BSc (Hons)
Technical Manager
On behalf of Roma Medical Aids Ltd.
Date of Issue: 11/06/24
Date of expiry: 11/06/34

A handwritten signature in black ink, appearing to read "R Pitt", written over a horizontal line.