

DECLARATION OF CONFORMITY



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

Classification: Class 1 Medical Device

Basic UDI-DI (GMN): 5055721241051UG

GMDN Code: 41051 – Bath board

Intended Use: A device in the form of a flat board designed to be sat upon by an adult patient who is bathing in a bath (usually while being attended/assisted) to elevate the patient out of the water except for the feet. The patient is typically disabled, infirm, or undergoing medical treatment and cannot sit normally in a bath. The device typically includes a solid or ribbed flat seat and is secured across the rim of the bath; it is typically made of water-resistant or waterproof materials. The device may be used in a hospital, institution, or home.

Catalogue/Reference (REF) of included products:

4100	4245	4608	4627H
4228	4245/NS	4612	4628H
4228W	4606	4626H	

Manufacturer:

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

Company Registration No. 1869285

SRN: GB-MF-000013502

Authorised EU Representative:

StartDock Rotterdam B.V.
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 faint, stylized signature line.