

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): 5055721240539VC

GMDN Code: 40539 – Commode, manual

Intended Use: A non-active, manually-operated transportable device in the form of a chair with a built-in receptacle for collecting urine and faeces intended to enable a patient with a disability to urinate/defecate away from a bathroom or fixed toilet (e.g., during shower). Also known as a sanichair, it may include hydraulically-assisted seat height adjustment, and may or may not be supplied with wheels (castors).

Catalogue/Reference (REF) of included products:

3001	3191A	3514	4730/SS
3151	3200	3515	4740
3151/25	3200A	3521	4740/CV
3153	3275/4BC	3521/BLUE	4740/CV/SS
3175/4BC	3308	3521/PR	4740/SS
3175/ADJ/4BC	3308F	3521A	4740A/CV/SS
3175/FR	3310	3521A/NL	4740A/SS
3175/FR/P	3316	3521A/PR	4750/CV
3175/SB/FR	3326	3521AD	4750/CV/SS
3175BCD/4BC	3327	3521D	4750/SPECIAL
3190/4BC	3328	3521NL	4750/SS
3190/4BC/HD	3375/4BC	4140/4BC	4750A
3190/FR	3504	4141G/4BC	6330
3190A/4BC	3505	4700	
3190A/REV	3510	4730	
3191	3510A	4730/SPECIAL	

Manufacturer:

Roma Medical Aids Ltd.
York Road
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