Valentine International Ltd.
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New Taipei City, Taiwan R.O.C.
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Declaration of Conformity

Manufacturer: Valentine International Ltd.
221 Hsichih District, New Taipei City
Taiwan R.O.C.

Authorized Representative: KOMAS Medical Technology GmbH
Sternstr. 67
40479 Dusseldorf, Germany

Products:

TESA Item No.	Val Item No.	Description	UDI-DI
TMS 298	10298/7/BAG	Wheelchair Ramp	4719879700299
TMS 698	12698	Rollator	4719879700282
TMS 490	10490	Walker/Wheelchair Bag	4719879700374
TMS 561	10561/U	Shower Bench	4719879700381
TMS 571	10571/NB	Shower Stool	4719879700336
TMS 585	10585NB	Mobile Commode Chair	4719879700329
TMS 764	10764L	Hi Rise Toilet Seat with Lid	4719879700046
TMS 766	10766L	Hi Rise Toilet Seat with Lid	4719879700268
TMS 511	11511/NB	Transfer Bench	4719879700398
TMS 551	11551/CH	K/D Shower Bench without Back	4719879700367
TMS 551B	11551/B/CH	K/D Shower Bench with Back	4719879700350
TMS 336	13336	Shower Chair	4719879700343
TMS 798	12798R20/C	Commode Liner	4719879700312
TMS 164	20164	Toilet Paper Holder	4719879700305

I hereby declare that the products specified above are classified as class 1 devices, as in conformity with the requirements of the EU Medical Device Regulation (EU) MDR 2017/745. Valentine International Ltd. products are manufactured in both China and Taiwan R.O.C.

For the evaluation regarding Class I device (Risk class in accordance with the Rule 1 set out in Annex VIII of the Regulation), the following harmonized standards are applied.

- EN ISO13485:2016 Medical Devices -Quality management systems – Requirements for regulatory purposes.
- EN ISO14971:2019 Medical Devices – Application of Risk Management
- EN ISO 15223-1: 2016 Medical Devices – Symbols to be used with medical devices, labels, labelling and information to be supplied – Part 1: General requirements
- EN 62366-1:2015 Medical devices Part 1 – Application of usability engineering to medical devices.

This was verified with conformity evaluation procedures according to Medical Device Regulation Annex VIII.

Authorized signature:

Ivory Hung
Manager

Date:
Place of signing: Taiwan ROC