

DICHIARAZIONE DI CONFORMITA'



Ai sensi del Regolamento UE 2017/745

L'azienda Demarta Virginio S.r.l. dichiara sotto la sua esclusiva responsabilità che i prodotti fabbricati ed immessi in commercio dalla stessa Demarta Virginio S.r.l.:

BASIC UDI-DI CARROZZINE MANUALI DA TRANSITO: 8052141080104BGB

Articolo	Codice	UDI-DI / EAN
Carrozzina da Transito Viky Transit • 41 cm	01.04.320S41FD	08052141089156
Carrozzina da Transito Viky Transit • 43 cm	01.04.320S43FD	08052141089163
Carrozzina da Transito Viky Transit • 46 cm	01.04.320S46FD	08052141089170
Carrozzina da Transito Viky Transit • 48 cm	01.04.320S48FD	08052141089187
Carrozzina da Transito Viky Transit Plus • 41 cm	01.04.320D41FD	08052141089194
Carrozzina da Transito Viky Transit Plus • 43 cm	01.04.320D43FD	08052141089200
Carrozzina da Transito Viky Transit Plus • 46 cm	01.04.320D46FD	08052141089217
Carrozzina da Transito Viky Transit Plus • 48 cm	01.04.320D48FD	08052141089309
Carrozzina da Transito Viky Transit Plus • 50 cm	01.04.320D50FD	08052141089316
Carrozzina da Transito Viky Transit Light • 41 cm	01.04.640DQR41FD	08052141089323
Carrozzina da Transito Viky Transit Light • 43 cm	01.04.640DQR43FD	08052141089330
Carrozzina da Transito Viky Transit Light • 46 cm	01.04.640DQR46FD	08052141089347
Carrozzina da Transito Viky Transit Light • 48 cm	01.04.640DQR48FD	08052141089354
Carrozzina da Transito Viky Transit Special • 41 cm	01.04.330S41FD	08056697943023
Carrozzina da Transito Viky Transit Special • 43 cm	01.04.330S43FD	08056697943030
Carrozzina da Transito Viky Transit Special • 46 cm	01.04.330S46FD	08056697943047
Carrozzina da Transito Viky Transit Special • 48 cm	01.04.330S48FD	08056697943054

sono conformi alle disposizioni applicabili del **Regolamento 2017/745 sui Dispositivi Medici del 5 aprile 2017**.

La Demarta Virginio S.r.l. dichiara, inoltre, quanto segue:

- I dispositivi soddisfano i requisiti generali di sicurezza e prestazione così come richiesti dall'allegato I del regolamento 2017/745 come prescritto dall'allegato IV del suddetto regolamento.
- I dispositivi in tabella **NON SONO STRUMENTI DI MISURA**.
- I dispositivi in tabella **NON SONO DESTINATI AD INDAGINI CLINICHE**.
- I dispositivi in tabella vengono commercializzati in **confezione NON STERILE**.
- I dispositivi in tabella sono da considerarsi come appartenenti alla **classe I** in conformità a quanto stabilito dall'allegato VIII del suddetto regolamento.

Cerrione, 01/06/2023

DEMARTA VIRGINIO S.r.l.
Dott. Virginio Belletti



DECLARATION OF CONFORMITY



Regulation 2017/745 on MEDICAL DEVICES of 5 April 2017

Demarta Virginio S.r.l. declares under its sole responsibility that the products made and traded by Demarta Virginio S.r.l. and belonging to the group of:

BASIC UDI-DI TRANSPORT WHEELCHAIRS: 8052141080104BGB

Article	Code	UDI-DI / EAN
Transport Wheelchair Viky Transit • 41 cm	01.04.320S41FD	08052141089156
Transport Wheelchair Viky Transit • 43 cm	01.04.320S43FD	08052141089163
Transport Wheelchair Viky Transit • 46 cm	01.04.320S46FD	08052141089170
Transport Wheelchair Viky Transit • 48 cm	01.04.320S48FD	08052141089187
Transport Wheelchair Viky Transit Plus • 41 cm	01.04.320D41FD	08052141089194
Transport Wheelchair Viky Transit Plus • 43 cm	01.04.320D43FD	08052141089200
Transport Wheelchair Viky Transit Plus • 46 cm	01.04.320D46FD	08052141089217
Transport Wheelchair Viky Transit Plus • 48 cm	01.04.320D48FD	08052141089309
Transport Wheelchair Viky Transit Plus • 50 cm	01.04.320D50FD	08052141089316
Transport Wheelchair Viky Transit Light • 41 cm	01.04.640DQR41FD	08052141089323
Transport Wheelchair Viky Transit Light • 43 cm	01.04.640DQR43FD	08052141089330
Transport Wheelchair Viky Transit Light • 46 cm	01.04.640DQR46FD	08052141089347
Transport Wheelchair Viky Transit Light • 48 cm	01.04.640DQR48FD	08052141089354
Transport Wheelchair Viky Transit Special • 41 cm	01.04.330S41FD	08056697943023
Transport Wheelchair Viky Transit Special • 43 cm	01.04.330S43FD	08056697943030
Transport Wheelchair Viky Transit Special • 46 cm	01.04.330S46FD	08056697943047
Transport Wheelchair Viky Transit Special • 48 cm	01.04.330S48FD	08056697943054

comply with the applicable provisions of the **2017/745 Regulation on Medical Devices of 5 April 2017**.

Demarta Virginio S.r.l. guarantees and declares under its sole responsibility what follows:

- The devices satisfy the requirements of general safety and performance requested by the Annex I of regulation 2017/745 as laid down by the Annex IV of the above mentioned regulation.
- The devices **ARE NOT MEASURING INSTRUMENTS**.
- The devices **ARE NOT MADE FOR CLINICAL TESTS**.
- The devices are packed in **NON-STERILE BOX**.
- The devices belong to **class I** in accordance with the provisions of Annex VIII of the above mentioned regulation.

Cerrione, 01/06/2023

DEMARTA VIRGINIO S.r.l.
Dott. Virginio Belletti

