

DICHIARAZIONE DI CONFORMITA'



Ai sensi del Regolamento UE 2017/745

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

BASIC UDI-DI CARROZZINE MANUALI AUTOSPINTA: 8052141080104AG9

Articolo	Codice	UDI-DI / EAN
Carrozzina ad Autospinta Viky Single Cross • 41 cm	01.04.310S41FD	08052141088937
Carrozzina ad Autospinta Viky Single Cross • 43 cm	01.04.310S43FD	08052141088944
Carrozzina ad Autospinta Viky Single Cross • 46 cm	01.04.310S46FD	08052141088951
Carrozzina ad Autospinta Viky Single Cross • 48 cm	01.04.310S48FD	08052141088968
Carrozzina ad Autospinta Viky Double Cross • 41 cm	01.04.310D41FD	08052141088975
Carrozzina ad Autospinta Viky Double Cross • 43 cm	01.04.310D43FD	08052141088982
Carrozzina ad Autospinta Viky Double Cross • 46 cm	01.04.310D46FD	08052141088999
Carrozzina ad Autospinta Viky Double Cross • 48 cm	01.04.310D48FD	08052141089002
Carrozzina ad Autospinta Viky Double Cross • 50 cm	01.04.310D50FD	08052141089019
Carrozzina ad Autospinta Viky Exchange • 41 cm	01.04.41ESQR41FD	08052141089026
Carrozzina ad Autospinta Viky Exchange • 43 cm	01.04.41ESQR43FD	08052141089033
Carrozzina ad Autospinta Viky Exchange • 46 cm	01.04.41ESQR46FD	08052141089040
Carrozzina ad Autospinta Viky Exchange • 48 cm	01.04.41ESQR48FD	08052141089057
Carrozzina ad Autospinta Viky Exchange Plus • 41 cm	01.04.41EDQR41FD	08052141089064
Carrozzina ad Autospinta Viky Exchange Plus • 43 cm	01.04.41EDQR43FD	08052141089071
Carrozzina ad Autospinta Viky Exchange Plus • 46 cm	01.04.41EDQR46FD	08052141089088
Carrozzina ad Autospinta Viky Exchange Plus • 48 cm	01.04.41EDQR48FD	08052141089095
Carrozzina ad Autospinta Viky Exchange Plus • 50 cm	01.04.41EDQR50FD	08052141089101
Carrozzina ad Autospinta Viky Slim • 41 cm	01.04.340D41FD	08052141089118
Carrozzina ad Autospinta Viky Slim • 43 cm	01.04.340D43FD	08052141089125
Carrozzina ad Autospinta Viky Slim • 46 cm	01.04.340D46FD	08052141089132
Carrozzina ad Autospinta Viky Kid • 35 cm	01.04.310S35FD	08052141089149
Carrozzina Leggera ad Autospinta Viky Light • 41 cm	01.04.630DQR41FD	08052141089224
Carrozzina Leggera ad Autospinta Viky Light • 43 cm	01.04.630DQR43FD	08052141089231
Carrozzina Leggera ad Autospinta Viky Light • 46 cm	01.04.630DQR46FD	08052141089248
Carrozzina Leggera ad Autospinta Viky Light • 48 cm	01.04.630DQR48FD	08052141089255
Carrozzina Leggera ad Autospinta Viky Comfy Light • 41 cm	01.04.63EDQR41FD	08052141089262
Carrozzina Leggera ad Autospinta Viky Comfy Light • 43 cm	01.04.63EDQR43FD	08052141089279
Carrozzina Leggera ad Autospinta Viky Comfy Light • 46 cm	01.04.63EDQR46FD	08052141089286
Carrozzina Leggera ad Autospinta Viky Comfy Light • 48 cm	01.04.63EDQR48FD	08052141089293

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

La Demarta Virginio S.a.S. 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.

Pollone, 26/05/2021

DEMARTA VIRGINIO S.a.S.
Dott. Virginio Belletti



DECLARATION OF CONFORMITY



Regulation 2017/745 on MEDICAL DEVICES of 5 April 2017

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

BASIC UDI-DI MANUAL WHEELCHAIRS: 8052141080104AG9

Article	Code	UDI-DI / EAN
Manual Wheelchair Viky Single Cross • 41 cm	01.04.310S41FD	08052141088937
Manual Wheelchair Viky Single Cross • 43 cm	01.04.310S43FD	08052141088944
Manual Wheelchair Viky Single Cross • 46 cm	01.04.310S46FD	08052141088951
Manual Wheelchair Viky Single Cross • 48 cm	01.04.310S48FD	08052141088968
Manual Wheelchair Viky Double Cross • 41 cm	01.04.310D41FD	08052141088975
Manual Wheelchair Viky Double Cross • 43 cm	01.04.310D43FD	08052141088982
Manual Wheelchair Viky Double Cross • 46 cm	01.04.310D46FD	08052141088999
Manual Wheelchair Viky Double Cross • 48 cm	01.04.310D48FD	08052141089002
Manual Wheelchair Viky Double Cross • 50 cm	01.04.310D50FD	08052141089019
Manual Wheelchair Viky Exchange • 41 cm	01.04.41ESQR41FD	08052141089026
Manual Wheelchair Viky Exchange • 43 cm	01.04.41ESQR43FD	08052141089033
Manual Wheelchair Viky Exchange • 46 cm	01.04.41ESQR46FD	08052141089040
Manual Wheelchair Viky Exchange • 48 cm	01.04.41ESQR48FD	08052141089057
Manual Wheelchair Viky Exchange Plus • 41 cm	01.04.41EDQR41FD	08052141089064
Manual Wheelchair Viky Exchange Plus • 43 cm	01.04.41EDQR43FD	08052141089071
Manual Wheelchair Viky Exchange Plus • 46 cm	01.04.41EDQR46FD	08052141089088
Manual Wheelchair Viky Exchange Plus • 48 cm	01.04.41EDQR48FD	08052141089095
Manual Wheelchair Viky Exchange Plus • 50 cm	01.04.41EDQR50FD	08052141089101
Manual Wheelchair Viky Slim • 41 cm	01.04.340D41FD	08052141089118
Manual Wheelchair Viky Slim • 43 cm	01.04.340D43FD	08052141089125
Manual Wheelchair Viky Slim • 46 cm	01.04.340D46FD	08052141089132
Manual Wheelchair Viky Kid • 35 cm	01.04.310S35FD	08052141089149
Wheelchair Viky Light • 41 cm	01.04.630DQR41FD	08052141089224
Wheelchair Viky Light • 43 cm	01.04.630DQR43FD	08052141089231
Wheelchair Viky Light • 46 cm	01.04.630DQR46FD	08052141089248
Wheelchair Viky Light • 48 cm	01.04.630DQR48FD	08052141089255
Wheelchair Viky Comfy Light • 41 cm	01.04.63EDQR41FD	08052141089262
Wheelchair Viky Comfy Light • 43 cm	01.04.63EDQR43FD	08052141089279
Wheelchair Viky Comfy Light • 46 cm	01.04.63EDQR46FD	08052141089286
Wheelchair Viky Comfy Light • 48 cm	01.04.63EDQR48FD	08052141089293

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

Demarta Virginio S.a.S. 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.

Pollone, 26/05/2021

DEMARTA VIRGINIO S.a.S.
Dott. Virginio Belletti

