

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 CARROZZINE 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

