

DICHIARAZIONE DI CONFORMITA'



L'azienda Demarta Virginio S.a.S. dichiara, sotto la propria responsabilità, che i seguenti dispositivi medici marchiati CE:

| Articolo | Codice |
|---|------------------|
| Carrozzina ad Autospinta Viky Single Cross • 41 cm | 01.04.310S41FD |
| Carrozzina ad Autospinta Viky Single Cross • 43 cm | 01.04.310S43FD |
| Carrozzina ad Autospinta Viky Single Cross • 46 cm | 01.04.310S46FD |
| Carrozzina ad Autospinta Viky Single Cross • 48 cm | 01.04.310S48FD |
| Carrozzina ad Autospinta Viky Double Cross • 41 cm | 01.04.310D41FD |
| Carrozzina ad Autospinta Viky Double Cross • 43 cm | 01.04.310D43FD |
| Carrozzina ad Autospinta Viky Double Cross • 46 cm | 01.04.310D46FD |
| Carrozzina ad Autospinta Viky Double Cross • 48 cm | 01.04.310D48FD |
| Carrozzina ad Autospinta Viky Exchange • 41 cm | 01.04.41ESQR41FD |
| Carrozzina ad Autospinta Viky Exchange • 43 cm | 01.04.41ESQR43FD |
| Carrozzina ad Autospinta Viky Exchange • 46 cm | 01.04.41ESQR46FD |
| Carrozzina ad Autospinta Viky Exchange • 48 cm | 01.04.41ESQR48FD |
| Carrozzina ad Autospinta Viky Exchange Plus • 41 cm | 01.04.41EDQR41FD |
| Carrozzina ad Autospinta Viky Exchange Plus • 43 cm | 01.04.41EDQR43FD |
| Carrozzina ad Autospinta Viky Exchange Plus • 46 cm | 01.04.41EDQR46FD |
| Carrozzina ad Autospinta Viky Exchange Plus • 48 cm | 01.04.41EDQR48FD |
| Carrozzina ad Autospinta Viky Slim • 41 cm | 01.04.340D41FD |
| Carrozzina ad Autospinta Viky Slim • 43 cm | 01.04.340D43FD |
| Carrozzina ad Autospinta Viky Slim • 46 cm | 01.04.340D46FD |
| Carrozzina ad Autospinta Viky Kid • 35 cm | 01.04.310S35FD |

sono classificati come classe di rischio I non sterile, in accordo alla regola 1 dell'Allegato IX della Direttiva 93/42/CEE.

Gli articoli soprariportati, inoltre:

- Rispettano le misure definite dai requisiti essenziali di salute e sicurezza della Direttiva 93/42/CEE (recepita in Italia con D.lgs 46/97), Allegato I e VII.
- Sono conformi a tutti gli standard europei ad essi applicabili.

Pollone, 21/02/2020

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



DECLARATION OF CONFORMITY



Demarta Virginio S.a.S. declares under his sole responsibility that the CE marked devices:

| Article | Code |
|--|------------------|
| Manual Wheelchair Viky Single Cross • 41 cm | 01.04.310S41FD |
| Manual Wheelchair Viky Single Cross • 43 cm | 01.04.310S43FD |
| Manual Wheelchair Viky Single Cross • 46 cm | 01.04.310S46FD |
| Manual Wheelchair Viky Single Cross • 48 cm | 01.04.310S48FD |
| Manual Wheelchair Viky Double Cross • 41 cm | 01.04.310D41FD |
| Manual Wheelchair Viky Double Cross • 43 cm | 01.04.310D43FD |
| Manual Wheelchair Viky Double Cross • 46 cm | 01.04.310D46FD |
| Manual Wheelchair Viky Double Cross • 48 cm | 01.04.310D48FD |
| Manual Wheelchair Viky Exchange • 41 cm | 01.04.41ESQR41FD |
| Manual Wheelchair Viky Exchange • 43 cm | 01.04.41ESQR43FD |
| Manual Wheelchair Viky Exchange • 46 cm | 01.04.41ESQR46FD |
| Manual Wheelchair Viky Exchange • 48 cm | 01.04.41ESQR48FD |
| Manual Wheelchair Viky Exchange Plus • 41 cm | 01.04.41EDQR41FD |
| Manual Wheelchair Viky Exchange Plus • 43 cm | 01.04.41EDQR43FD |
| Manual Wheelchair Viky Exchange Plus • 46 cm | 01.04.41EDQR46FD |
| Manual Wheelchair Viky Exchange Plus • 48 cm | 01.04.41EDQR48FD |
| Manual Wheelchair Viky Slim • 41 cm | 01.04.340D41FD |
| Manual Wheelchair Viky Slim • 43 cm | 01.04.340D43FD |
| Manual Wheelchair Viky Slim • 46 cm | 01.04.340D46FD |
| Manual Wheelchair Viky Kid • 35 cm | 01.04.310S35FD |

have been classified as class I, according to annex IX MDD 93/42/EEC, rule 1.

The above-mentioned articles also comply with:

- The measures defined by the essential health and safety requirements of Directive 93/42/EEC (implemented in Italy with Decree 46/97) annex I and VII.
- All European standards applicable to them.

Pollone, 21/02/2020

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Dott. Virginio Belletti

