

DICHIARAZIONE DI CONFORMITA'



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

Profilo 6 cm • Una valvola		Profilo 6 cm • Due valvole		Profilo 10 cm • Una valvola		Profilo 10 cm • Due valvole	
Codice	Misure (cm)	Codice	Misure (cm)	Codice	Misure (cm)	Codice	Misure (cm)
05.01.1V3636-6	36 x 36 x 6	05.01.2V3636-6	36 x 36 x 6	05.01.1V3636-10	36 x 36 x 10	05.01.2V3636-10	36 x 36 x 10
05.01.1V4036-6	40 x 36 x 6	05.01.2V4036-6	40 x 36 x 6	05.01.1V4036-10	40 x 36 x 10	05.01.2V4036-10	40 x 36 x 10
05.01.1V3640-6	36 x 40 x 6	05.01.2V3640-6	36 x 40 x 6	05.01.1V3640-10	36 x 40 x 10	05.01.2V3640-10	36 x 40 x 10
05.01.1V4040-6	40 x 40 x 6	05.01.2V4040-6	40 x 40 x 6	05.01.1V4040-10	40 x 40 x 10	05.01.2V4040-10	40 x 40 x 10
05.01.1V4640-6	46 x 40 x 6	05.01.2V4640-6	46 x 40 x 6	05.01.1V4640-10	46 x 40 x 10	05.01.2V4640-10	46 x 40 x 10
05.01.1V4046-6	40 x 46 x 6	05.01.2V4046-6	40 x 46 x 6	05.01.1V4046-10	40 x 46 x 10	05.01.2V4046-10	40 x 46 x 10
05.01.1V4646-6	46 x 46 x 6	05.01.2V4646-6	46 x 46 x 6	05.01.1V4646-10	46 x 46 x 10	05.01.2V4646-10	46 x 46 x 10
05.01.1V5046-6	50 x 46 x 6	05.01.2V5046-6	50 x 46 x 6	05.01.1V5046-10	50 x 46 x 10	05.01.2V5046-10	50 x 46 x 10
05.01.1V4650-6	46 x 50 x 6	05.01.2V4650-6	46 x 50 x 6	05.01.1V4650-10	46 x 50 x 10	05.01.2V4650-10	46 x 50 x 10
05.01.1V5050-6	50 x 50 x 6	05.01.2V5050-6	50 x 50 x 6	05.01.1V5050-10	50 x 50 x 10	05.01.2V5050-10	50 x 50 x 10
05.01.1V5650-6	56 x 50 x 6	05.01.2V5650-6	56 x 50 x 6	05.01.1V5650-10	56 x 50 x 10	05.01.2V5650-10	56 x 50 x 10
05.01.1V5056-6	50 x 56 x 6	05.01.2V5056-6	50 x 56 x 6	05.01.1V5056-10	50 x 56 x 10	05.01.2V5056-10	50 x 56 x 10
05.01.1V5656-6	56 x 56 x 6	05.01.2V5656-6	56 x 56 x 6	05.01.1V5656-10	56 x 56 x 10	05.01.2V5656-10	56 x 56 x 10
05.01.1V6056-6	60 x 56 x 6	05.01.2V6056-6	60 x 56 x 6	05.01.1V6056-10	60 x 56 x 10	05.01.2V6056-10	60 x 56 x 10
05.01.1V5660-6	56 x 60 x 6	05.01.2V5660-6	56 x 60 x 6	05.01.1V5660-10	56 x 60 x 10	05.01.2V5660-10	56 x 60 x 10
05.01.1V6060-6	60 x 60 x 6	05.01.2V6060-6	60 x 60 x 6	05.01.1V6060-10	60 x 60 x 10	05.01.2V6060-10	60 x 60 x 10
05.01.1V6650-6	66 x 50 x 6	05.01.2V6650-6	66 x 50 x 6	05.01.1V6650-10	66 x 50 x 10	05.01.2V6650-10	66 x 50 x 10
05.01.1V6660-6	66 x 60 x 6	05.01.2V6660-6	66 x 60 x 6	05.01.1V6660-10	66 x 60 x 10	05.01.2V6660-10	66 x 60 x 10
05.01.1V6066-6	60 x 66 x 6	05.01.2V6066-6	60 x 66 x 6	05.01.1V6066-10	60 x 66 x 10	05.01.2V6066-10	60 x 66 x 10
05.01.1V6666-6	66 x 66 x 6	05.01.2V6666-6	66 x 66 x 6	05.01.1V6666-10	66 x 66 x 10	05.01.2V6666-10	66 x 66 x 10


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, 18 Febbraio 2019

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:

6 cm Height • 1 valve		6 cm Height • 2 valves		10 cm Height • 1 valve		10 cm Height • 2 valves	
Code	Dimensions (cm)	Code	Dimensions (cm)	Code	Dimensions (cm)	Code	Dimensions (cm)
05.01.1V3636-6	36 x 36 x 6	05.01.2V3636-6	36 x 36 x 6	05.01.1V3636-10	36 x 36 x 10	05.01.2V3636-10	36 x 36 x 10
05.01.1V4036-6	40 x 36 x 6	05.01.2V4036-6	40 x 36 x 6	05.01.1V4036-10	40 x 36 x 10	05.01.2V4036-10	40 x 36 x 10
05.01.1V3640-6	36 x 40 x 6	05.01.2V3640-6	36 x 40 x 6	05.01.1V3640-10	36 x 40 x 10	05.01.2V3640-10	36 x 40 x 10
05.01.1V4040-6	40 x 40 x 6	05.01.2V4040-6	40 x 40 x 6	05.01.1V4040-10	40 x 40 x 10	05.01.2V4040-10	40 x 40 x 10
05.01.1V4640-6	46 x 40 x 6	05.01.2V4640-6	46 x 40 x 6	05.01.1V4640-10	46 x 40 x 10	05.01.2V4640-10	46 x 40 x 10
05.01.1V4046-6	40 x 46 x 6	05.01.2V4046-6	40 x 46 x 6	05.01.1V4046-10	40 x 46 x 10	05.01.2V4046-10	40 x 46 x 10
05.01.1V4646-6	46 x 46 x 6	05.01.2V4646-6	46 x 46 x 6	05.01.1V4646-10	46 x 46 x 10	05.01.2V4646-10	46 x 46 x 10
05.01.1V5046-6	50 x 46 x 6	05.01.2V5046-6	50 x 46 x 6	05.01.1V5046-10	50 x 46 x 10	05.01.2V5046-10	50 x 46 x 10
05.01.1V4650-6	46 x 50 x 6	05.01.2V4650-6	46 x 50 x 6	05.01.1V4650-10	46 x 50 x 10	05.01.2V4650-10	46 x 50 x 10
05.01.1V5050-6	50 x 50 x 6	05.01.2V5050-6	50 x 50 x 6	05.01.1V5050-10	50 x 50 x 10	05.01.2V5050-10	50 x 50 x 10
05.01.1V5650-6	56 x 50 x 6	05.01.2V5650-6	56 x 50 x 6	05.01.1V5650-10	56 x 50 x 10	05.01.2V5650-10	56 x 50 x 10
05.01.1V5056-6	50 x 56 x 6	05.01.2V5056-6	50 x 56 x 6	05.01.1V5056-10	50 x 56 x 10	05.01.2V5056-10	50 x 56 x 10
05.01.1V5656-6	56 x 56 x 6	05.01.2V5656-6	56 x 56 x 6	05.01.1V5656-10	56 x 56 x 10	05.01.2V5656-10	56 x 56 x 10
05.01.1V6056-6	60 x 56 x 6	05.01.2V6056-6	60 x 56 x 6	05.01.1V6056-10	60 x 56 x 10	05.01.2V6056-10	60 x 56 x 10
05.01.1V5660-6	56 x 60 x 6	05.01.2V5660-6	56 x 60 x 6	05.01.1V5660-10	56 x 60 x 10	05.01.2V5660-10	56 x 60 x 10
05.01.1V6060-6	60 x 60 x 6	05.01.2V6060-6	60 x 60 x 6	05.01.1V6060-10	60 x 60 x 10	05.01.2V6060-10	60 x 60 x 10
05.01.1V6650-6	66 x 50 x 6	05.01.2V6650-6	66 x 50 x 6	05.01.1V6650-10	66 x 50 x 10	05.01.2V6650-10	66 x 50 x 10
05.01.1V6660-6	66 x 60 x 6	05.01.2V6660-6	66 x 60 x 6	05.01.1V6660-10	66 x 60 x 10	05.01.2V6660-10	66 x 60 x 10
05.01.1V6066-6	60 x 66 x 6	05.01.2V6066-6	60 x 66 x 6	05.01.1V6066-10	60 x 66 x 10	05.01.2V6066-10	60 x 66 x 10
05.01.1V6666-6	66 x 66 x 6	05.01.2V6666-6	66 x 66 x 6	05.01.1V6666-10	66 x 66 x 10	05.01.2V6666-10	66 x 66 x 10

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, 18 February 2019

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

