

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


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, 28/01/2021

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

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, 28/01/2021

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Dott. Virginio Belletti

