



## 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 CUSCINI AD ARIA: 8052141080501EH4

Articolo	Codice	UDI-DI / EAN
CUSHION AIR 36x36x10 cm 1 Valvola	05.01.1V3636-10	08052141081884
CUSHION AIR 40x36x10 cm 1 Valvola	05.01.1V4036-10	08052141081891
CUSHION AIR 36x40x10 cm 1 Valvola	05.01.1V3640-10	08052141081907
CUSHION AIR 40x40x10 cm 1 Valvola	05.01.1V4040-10	08052141081914
CUSHION AIR 46x40x10 cm 1 Valvola	05.01.1V4640-10	08052141081921
CUSHION AIR 40X46x10 cm 1 Valvola	05.01.1V4046-10	08052141081938
CUSHION AIR 46X46x10 cm 1 Valvola	05.01.1V4646-10	08052141081945
CUSHION AIR 50X46x10 cm 1 Valvola	05.01.1V5046-10	08052141081952
CUSHION AIR 46X50x10 cm 1 Valvola	05.01.1V4650-10	08052141081969
CUSHION AIR 50X50x10 cm 1 Valvola	05.01.1V5050-10	08052141081976
CUSHION AIR 56X50x10 cm 1 Valvola	05.01.1V5650-10	08052141081983
CUSHION AIR 50X56x10 cm 1 Valvola	05.01.1V5056-10	08052141081990
CUSHION AIR 56X56x10 cm 1 Valvola	05.01.1V5656-10	08052141082003
CUSHION AIR 60X56x10 cm 1 Valvola	05.01.1V6056-10	08052141082010
CUSHION AIR 56X60x10 cm 1 Valvola	05.01.1V5660-10	08052141082027
CUSHION AIR 60X60x10 cm 1 Valvola	05.01.1V6060-10	08052141082034
CUSHION AIR 66X50x10 cm 1 Valvola	05.01.1V6650-10	08052141082041
CUSHION AIR 66X60x10 cm 1 Valvola	05.01.1V6660-10	08052141082058
CUSHION AIR 60X66x10 cm 1 Valvola	05.01.1V6066-10	08052141082065
CUSHION AIR 36x36x10 cm 2 Valvole	05.01.2V3636-10	08052141082072
CUSHION AIR 40x36x10 cm 2 Valvole	05.01.2V4036-10	08052141082089
CUSHION AIR 36x40x10 cm 2 Valvole	05.01.2V3640-10	08052141082096
CUSHION AIR 40x40x10 cm 2 Valvole	05.01.2V4040-10	08052141082102
CUSHION AIR 46x40x10 cm 2 Valvole	05.01.2V4640-10	08052141082119
CUSHION AIR 40X46x10 cm 2 Valvole	05.01.2V4046-10	08052141082126
CUSHION AIR 46X46x10 cm 2 Valvole	05.01.2V4646-10	08052141082133
CUSHION AIR 50X46x10 cm 2 Valvole	05.01.2V5046-10	08052141082140
CUSHION AIR 46X50x10 cm 2 Valvole	05.01.2V4650-10	08052141082157
CUSHION AIR 50X50x10 cm 2 Valvole	05.01.2V5050-10	08052141082164
CUSHION AIR 56X50x10 cm 2 Valvole	05.01.2V5650-10	08052141082171
CUSHION AIR 50X56x10 cm 2 Valvole	05.01.2V5056-10	08052141082188
CUSHION AIR 56X56x10 cm 2 Valvole	05.01.2V5656-10	08052141082195
CUSHION AIR 60X56x10 cm 2 Valvola	05.01.2V6056-10	08052141082201
CUSHION AIR 56X60x10 cm 2 Valvola	05.01.2V5660-10	08052141082218
CUSHION AIR 60X60x10 cm 2 Valvole	05.01.2V6060-10	08052141082225
CUSHION AIR 66X50x10 cm 2 Valvole	05.01.2V6650-10	08052141082232
CUSHION AIR 66X60x10 cm 2 Valvole	05.01.2V6660-10	08052141082249
CUSHION AIR 60X66x10 cm 2 Valvole	05.01.2V6066-10	08052141082256

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 FOR AIR LOW PRESSURE CUSHIONS: 8052141080501EH4

Article	Code	UDI-DI / EAN
CUSHION AIR 36x36x10 cm 1 Valve	05.01.1V3636-10	08052141081884
CUSHION AIR 40x36x10 cm 1 Valve	05.01.1V4036-10	08052141081891
CUSHION AIR 36x40x10 cm 1 Valve	05.01.1V3640-10	08052141081907
CUSHION AIR 40x40x10 cm 1 Valve	05.01.1V4040-10	08052141081914
CUSHION AIR 46x40x10 cm 1 Valve	05.01.1V4640-10	08052141081921
CUSHION AIR 40X46x10 cm 1 Valve	05.01.1V4046-10	08052141081938
CUSHION AIR 46X46x10 cm 1 Valve	05.01.1V4646-10	08052141081945
CUSHION AIR 50X46x10 cm 1 Valve	05.01.1V5046-10	08052141081952
CUSHION AIR 46X50x10 cm 1 Valve	05.01.1V4650-10	08052141081969
CUSHION AIR 50X50x10 cm 1 Valve	05.01.1V5050-10	08052141081976
CUSHION AIR 56X50x10 cm 1 Valve	05.01.1V5650-10	08052141081983
CUSHION AIR 50X56x10 cm 1 Valve	05.01.1V5056-10	08052141081990
CUSHION AIR 56X56x10 cm 1 Valve	05.01.1V5656-10	08052141082003
CUSHION AIR 60X56x10 cm 1 Valve	05.01.1V6056-10	08052141082010
CUSHION AIR 56X60x10 cm 1 Valve	05.01.1V5660-10	08052141082027
CUSHION AIR 60X60x10 cm 1 Valve	05.01.1V6060-10	08052141082034
CUSHION AIR 66X50x10 cm 1 Valve	05.01.1V6650-10	08052141082041
CUSHION AIR 66X60x10 cm 1 Valve	05.01.1V6660-10	08052141082058
CUSHION AIR 60X66x10 cm 1 Valve	05.01.1V6066-10	08052141082065
CUSHION AIR 36x36x10 cm 2 Valves	05.01.2V3636-10	08052141082072
CUSHION AIR 40x36x10 cm 2 Valves	05.01.2V4036-10	08052141082089
CUSHION AIR 36x40x10 cm 2 Valves	05.01.2V3640-10	08052141082096
CUSHION AIR 40x40x10 cm 2 Valves	05.01.2V4040-10	08052141082102
CUSHION AIR 46x40x10 cm 2 Valves	05.01.2V4640-10	08052141082119
CUSHION AIR 40X46x10 cm 2 Valves	05.01.2V4046-10	08052141082126
CUSHION AIR 46X46x10 cm 2 Valves	05.01.2V4646-10	08052141082133
CUSHION AIR 50X46x10 cm 2 Valves	05.01.2V5046-10	08052141082140
CUSHION AIR 46X50x10 cm 2 Valves	05.01.2V4650-10	08052141082157
CUSHION AIR 50X50x10 cm 2 Valves	05.01.2V5050-10	08052141082164
CUSHION AIR 56X50x10 cm 2 Valves	05.01.2V5650-10	08052141082171
CUSHION AIR 50X56x10 cm 2 Valves	05.01.2V5056-10	08052141082188
CUSHION AIR 56X56x10 cm 2 Valves	05.01.2V5656-10	08052141082195
CUSHION AIR 60X56x10 cm 2 Valves	05.01.2V6056-10	08052141082201
CUSHION AIR 56X60x10 cm 2 Valves	05.01.2V5660-10	08052141082218
CUSHION AIR 60X60x10 cm 2 Valves	05.01.2V6060-10	08052141082225
CUSHION AIR 66X50x10 cm 2 Valves	05.01.2V6650-10	08052141082232
CUSHION AIR 66X60x10 cm 2 Valves	05.01.2V6660-10	08052141082249
CUSHION AIR 60X66x10 cm 2 Valves	05.01.2V6066-10	08052141082256

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