



DICHIARAZIONE DI CONFORMITA'



Ai sensi del Regolamento UE 2017/745

SRN: IT-MF-000032546

L'azienda Demarta Virginio S.r.l. dichiara sotto la sua esclusiva responsabilità che i prodotti fabbricati ed immessi in commercio dalla stessa Demarta Virginio S.r.l.:

BASIC UDI-DI CUSCINI AD ARIA: 8052141080501EH4

Articolo	Codice	UDI-DI / EAN
CUSHION AIR 36x36x6 cm 1 Valvola	05.01.1V3636-6	08052141081457
CUSHION AIR 40x36x6 cm 1 Valvola	05.01.1V4036-6	08052141081464
CUSHION AIR 36x40x6 cm 1 Valvola	05.01.1V3640-6	08052141081471
CUSHION AIR 40x40x6 cm 1 Valvola	05.01.1V4040-6	08052141081488
CUSHION AIR 46x40x6 cm 1 Valvola	05.01.1V4640-6	08052141081495
CUSHION AIR 40x46x6 cm 1 Valvola	05.01.1V4046-6	08052141081501
CUSHION AIR 46x46x6 cm 1 Valvola	05.01.1V4646-6	08052141081518
CUSHION AIR 50x46x6 cm 1 Valvola	05.01.1V5046-6	08052141081525
CUSHION AIR 46x50x6 cm 1 Valvola	05.01.1V4650-6	08052141081532
CUSHION AIR 50x50x6 cm 1 Valvola	05.01.1V5050-6	08052141081549
CUSHION AIR 56x50x6 cm 1 Valvola	05.01.1V5650-6	08052141081556
CUSHION AIR 50x56x6 cm 1 Valvola	05.01.1V5056-6	08052141081563
CUSHION AIR 56x56x6 cm 1 Valvola	05.01.1V5656-6	08052141081570
CUSHION AIR 60x56x6 cm 1 Valvola	05.01.1V6056-6	08052141081587
CUSHION AIR 56x60x6 cm 1 Valvola	05.01.1V5660-6	08052141081594
CUSHION AIR 60x60x6 cm 1 Valvola	05.01.1V6060-6	08052141081600
CUSHION AIR 66x50x6 cm 1 Valvola	05.01.1V6650-6	08052141081617
CUSHION AIR 66x60x6 cm 1 Valvola	05.01.1V6660-6	08052141081624
CUSHION AIR 60x66x6 cm 1 Valvola	05.01.1V6066-6	08052141081631
CUSHION AIR 36x46x6 cm 1 Valvola	05.01.1V3646-6	08056697944259
CUSHION AIR 36x50x6 cm 1 Valvola	05.01.1V3650-6	08056697944266
CUSHION AIR 40x50x6 cm 1 Valvola	05.01.1V4050-6	08056697944273
CUSHION AIR 46x36x6 cm 1 Valvola	05.01.1V4636-6	08056697944280
CUSHION AIR 50x36x6 cm 1 Valvola	05.01.1V5036-6	08056697944297
CUSHION AIR 50x40x6 cm 1 Valvola	05.01.1V5040-6	08056697944440
CUSHION AIR 56x36x6 cm 1 Valvola	05.01.1V5636-6	08056697944303
CUSHION AIR 56x40x6 cm 1 Valvola	05.01.1V5640-6	08056697944310
CUSHION AIR 56x46x6 cm 1 Valvola	05.01.1V5646-6	08056697944327
CUSHION AIR 60x36x6 cm 1 Valvola	05.01.1V6036-6	08056697944334
CUSHION AIR 60x40x6 cm 1 Valvola	05.01.1V6040-6	08056697944341
CUSHION AIR 60x46x6 cm 1 Valvola	05.01.1V6046-6	08056697944358
CUSHION AIR 60x50x6 cm 1 Valvola	05.01.1V6050-6	08056697944365
CUSHION AIR 36x36x6 cm 2 Valvole	05.01.2V3636-6	08052141081648
CUSHION AIR 40x36x6 cm 2 Valvole	05.01.2V4036-6	08052141081655
CUSHION AIR 36x40x6 cm 2 Valvole	05.01.2V3640-6	08052141081662
CUSHION AIR 40x40x6 cm 2 Valvole	05.01.2V4040-6	08052141081679
CUSHION AIR 46x40x6 cm 2 Valvole	05.01.2V4640-6	08052141081686
CUSHION AIR 40x46x6 cm 2 Valvole	05.01.2V4046-6	08052141081693
CUSHION AIR 46x46x6 cm 2 Valvole	05.01.2V4646-6	08052141081709
CUSHION AIR 50x46x6 cm 2 Valvole	05.01.2V5046-6	08052141081716
CUSHION AIR 46x50x6 cm 2 Valvole	05.01.2V4650-6	08052141081723
CUSHION AIR 50x50x6 cm 2 Valvole	05.01.2V5050-6	08052141081730
CUSHION AIR 56x50x6 cm 2 Valvole	05.01.2V5650-6	08052141081747
CUSHION AIR 50x56x6 cm 2 Valvole	05.01.2V5056-6	08052141081754

CUSHION AIR 56X56x6 cm 2 Valvole	05.01.2V5656-6	08052141081761
CUSHION AIR 60X56x6 cm 2 Valvola	05.01.2V6056-6	08052141081778
CUSHION AIR 56X60x6 cm 2 Valvole	05.01.2V5660-6	08052141081785
CUSHION AIR 60X60x6 cm 2 Valvole	05.01.2V6060-6	08052141081792
CUSHION AIR 66X50x6 cm 2 Valvole	05.01.2V6650-6	08052141081808
CUSHION AIR 66X60x6 cm 2 Valvole	05.01.2V6660-6	08052141081815
CUSHION AIR 60X66x6 cm 2 Valvole	05.01.2V6066-6	08052141081822

sono conformi alle disposizioni applicabili del Regolamento 2017/745 sui Dispositivi Medici del 5 aprile 2017.

La Demarta Virginio S.r.l. 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.

Cerrione, 01/06/2023

DEMARTA VIRGINIO S.r.l.
Dott. Virginio Belletti





DECLARATION OF CONFORMITY



Regulation 2017/745 on MEDICAL DEVICES of 5 April 2017

SRN: IT-MF-000032546

Demarta Virginio S.r.l. declares under its sole responsibility that the products made and traded by Demarta Virginio S.r.l. and belonging to the group of:

BASIC UDI-DI FOR AIR LOW PRESSURE CUSHIONS: 8052141080501EH4

Article	Code	UDI-DI / EAN
CUSHION AIR 36x36x6 cm 1 Valve	05.01.1V3636-6	08052141081457
CUSHION AIR 40x36x6 cm 1 Valve	05.01.1V4036-6	08052141081464
CUSHION AIR 36x40x6 cm 1 Valve	05.01.1V3640-6	08052141081471
CUSHION AIR 40x40x6 cm 1 Valve	05.01.1V4040-6	08052141081488
CUSHION AIR 46x40x6 cm 1 Valve	05.01.1V4640-6	08052141081495
CUSHION AIR 40x46x6 cm 1 Valve	05.01.1V4046-6	08052141081501
CUSHION AIR 46x46x6 cm 1 Valve	05.01.1V4646-6	08052141081518
CUSHION AIR 50x46x6 cm 1 Valve	05.01.1V5046-6	08052141081525
CUSHION AIR 46x50x6 cm 1 Valve	05.01.1V4650-6	08052141081532
CUSHION AIR 50x50x6 cm 1 Valve	05.01.1V5050-6	08052141081549
CUSHION AIR 56x50x6 cm 1 Valve	05.01.1V5650-6	08052141081556
CUSHION AIR 50x56x6 cm 1 Valve	05.01.1V5056-6	08052141081563
CUSHION AIR 56x56x6 cm 1 Valve	05.01.1V5656-6	08052141081570
CUSHION AIR 60x56x6 cm 1 Valve	05.01.1V6056-6	08052141081587
CUSHION AIR 56x60x6 cm 1 Valve	05.01.1V5660-6	08052141081594
CUSHION AIR 60x60x6 cm 1 Valve	05.01.1V6060-6	08052141081600
CUSHION AIR 66x50x6 cm 1 Valve	05.01.1V6650-6	08052141081617
CUSHION AIR 66x60x6 cm 1 Valve	05.01.1V6660-6	08052141081624
CUSHION AIR 60x66x6 cm 1 Valve	05.01.1V6066-6	08052141081631
CUSHION AIR 36x46x6 cm 1 Valve	05.01.1V3646-6	08056697944259
CUSHION AIR 36x50x6 cm 1 Valve	05.01.1V3650-6	08056697944266
CUSHION AIR 40x50x6 cm 1 Valve	05.01.1V4050-6	08056697944273
CUSHION AIR 46x36x6 cm 1 Valve	05.01.1V4636-6	08056697944280
CUSHION AIR 50x36x6 cm 1 Valve	05.01.1V5036-6	08056697944297
CUSHION AIR 50x40x6 cm 1 Valve	05.01.1V5040-6	08056697944440
CUSHION AIR 56x36x6 cm 1 Valve	05.01.1V5636-6	08056697944303
CUSHION AIR 56x40x6 cm 1 Valve	05.01.1V5640-6	08056697944310
CUSHION AIR 56x46x6 cm 1 Valve	05.01.1V5646-6	08056697944327
CUSHION AIR 60x36x6 cm 1 Valve	05.01.1V6036-6	08056697944334

CUSHION AIR 60X40x6 cm 1 Valve	05.01.1V6040-6	08056697944341
CUSHION AIR 60X46x6 cm 1 Valve	05.01.1V6046-6	08056697944358
CUSHION AIR 60X50x6 cm 1 Valve	05.01.1V6050-6	08056697944365
CUSHION AIR 36x36x6 cm 2 Valves	05.01.2V3636-6	08052141081648
CUSHION AIR 40x36x6 cm 2 Valves	05.01.2V4036-6	08052141081655
CUSHION AIR 36x40x6 cm 2 Valves	05.01.2V3640-6	08052141081662
CUSHION AIR 40x40x6 cm 2 Valves	05.01.2V4040-6	08052141081679
CUSHION AIR 46x40x6 cm 2 Valves	05.01.2V4640-6	08052141081686
CUSHION AIR 40X46x6 cm 2 Valves	05.01.2V4046-6	08052141081693
CUSHION AIR 46X46x6 cm 2 Valves	05.01.2V4646-6	08052141081709
CUSHION AIR 50X46x6 cm 2 Valves	05.01.2V5046-6	08052141081716
CUSHION AIR 46X50x6 cm 2 Valves	05.01.2V4650-6	08052141081723
CUSHION AIR 50X50x6 cm 2 Valves	05.01.2V5050-6	08052141081730
CUSHION AIR 56X50x6 cm 2 Valves	05.01.2V5650-6	08052141081747
CUSHION AIR 50X56x6 cm 2 Valves	05.01.2V5056-6	08052141081754
CUSHION AIR 56X56x6 cm 2 Valves	05.01.2V5656-6	08052141081761
CUSHION AIR 60X56x6 cm 2 Valves	05.01.2V6056-6	08052141081778
CUSHION AIR 56X60x6 cm 2 Valves	05.01.2V5660-6	08052141081785
CUSHION AIR 60X60x6 cm 2 Valves	05.01.2V6060-6	08052141081792
CUSHION AIR 66X50x6 cm 2 Valves	05.01.2V6650-6	08052141081808
CUSHION AIR 66X60x6 cm 2 Valves	05.01.2V6660-6	08052141081815
CUSHION AIR 60X66x6 cm 2 Valves	05.01.2V6066-6	08052141081822
CUSHION AIR 50X40x6 cm 2 Valves	05.01.1V5040-6	08056697944440
CUSHION AIR 56X40x6 cm 2 Valves	05.01.1V5640-6	08056697944310
CUSHION AIR 56X46x6 cm 2 Valves	05.01.1V5646-6	08056697944327
CUSHION AIR 60X36x6 cm 2 Valves	05.01.1V6036-6	08056697944334
CUSHION AIR 60X40x6 cm 2 Valves	05.01.1V6040-6	08056697944341
CUSHION AIR 60X46x6 cm 2 Valves	05.01.1V6046-6	08056697944358
CUSHION AIR 60X50x6 cm 2 Valves	05.01.1V6050-6	08056697944365

comply with the applicable provisions of the 2017/745 Regulation on Medical Devices of 5 April 2017.

Demarta Virginio S.r.l. 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.

Cerrione, 01/06/2023

DEMARTA VIRGINIO S.r.l.
Dott. Virginio Belletti

