



DECLARATION OF CONFORMITY

BIOMATRIX S.r.l. (Unique registration number:), with registered office in CREMONA (CR), Via S. Anguissola, 22 and operational in CASTELVETRO (PC), Via M. Maffini, 23, as manufacturer of medical devices belonging to the CUSHIONS line , models:

Codice	Descrizione
CU01700	Water cushion in PVC without hole
CU01700F	Water cushion in PVC with hole
MA003CU	Single pillow for water mattress
CU01701	Cushion in silicone hollow fiber, 43x43 cm, with cover
CU01702O	Cushion in silicone hollow fiber (cotton / Obatex), 43x43 cm, without cover
CU01702A	Cushion in silicone hollow fiber 40x40 cm without cover
CU01702AF	Cushion in silicone hollow fiber, with hole, 40x40 cm, without cover
CU01702B	Cushion in silicone hollow fiber cm 45x45 without cover
CU01702BF	Cushion in silicone hollow fiber, with hole, 45x45 cm, without cover
CU01704	Fluid gel cushion, 40x40x4 cm, with cover
CU01705A	Fluid gel cushion, 40x40x5 cm, with cover
CU01705B	Fluid gel cushion, 45x45x5 cm, with cover
CU01705AF	Fluid gel cushion, with hole, 40x40x5 cm
CU01706A	Viscoelastic cushion, 42x42x5 cm, with cover
CU01706B	Viscoelastic cushion, 42x42x8 cm, with cover
CU01707S	Viscoelastic anatomic pillow, 38x38x7 cm, with cover
CU01707M	Viscoelastic anatomic pillow, 41x41x7 cm, with cover
CU01707L	Viscoelastic anatomic pillow, 43x43x7 cm, with cover
CU01707XL	Viscoelastic anatomic pillow, cm 45x45x7, with cover
CU01708	Polyurethane gel cushion, 40x40x3 cm, with cover
CU01708F	Polyurethane gel cushion, with hole, 40x40x3 cm, with cover
CU01709	Polyurethane gel cushion, 42x42x6 cm, with cover
CU01712	Anatomical anti-decubitus cushion in PU, with PU gel insert, cm 40x40, 42x42, 45x45, 47x47 - H 8, with cover
CU01713S	Anatomical pillow in self-modeling fluid gel, 41x41x8 cm, with cover
CU01713M	Anatomical pillow in self-modeling fluid gel, 43x43x8 cm, with cover
CU01713L	Anatomical pillow in self-modeling fluid gel, 45x45x8 cm, with cover
CU01711	Air bubble cushion in PVC with 1 or 2 removable valves 6/10 dimensions cm 36x36 - 36x40 - 40x36 - 40x40 - 40x46 - 46x40 - 46x46 - 50x46 - 46x50 - 50x50
CU01711.PU	Air bubble cushion in PU with 1 or 2 removable valves 6/10 dimensions cm 35x41 - 41x41 - 41x47 - 47x47
CU01711.N	Air bubble cushion in NEOPRENE with 1 or 2 removable valves 6/10 dimensions cm 40x40 - 40x46 - 46x46 - 50x46
CU01710	Cushion with intercommunicating air bubbles with 1 valve, removable cover with anti-slip complete h 6,5 / 10 dimensions cm 40x40, 44x40, 44x44
CU01714	Gel cushion 40x40x2.5 cm with gel insert in the sacral area
CU01716S	inflatable rubber donut for invalids diam. 35 in bag
CU01716M	inflatable rubber donut for invalids diam. 40 in a bag
CU01716L	inflatable rubber donut for invalids diam. 43 in bag
CU01716XL	inflatable rubber donut for invalids diam. 45 in bag
CU01717	round foam donut

CU01718	horseshoe foam donut
CU01719	Foam PU cushion for wheelchair with zip and laces

- comply with the essential requirements and provisions of Regulation (EU) 2017/745 (MDR), as per the Technical File filed at the company;
- the basic UDI-DI code is: 805411731CU017XXZA;
- Common Specifications have not been used for the compliance of the aforementioned medical devices;
- are manufactured in accordance with the Quality System that meets the requirements set out in Annex II + III of the Regulation.

CASTELVETRO (PC), 01/03/2021

Maria Grazia Mancini
Legale Rappresentante



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