



CE DECLARATION OF CONFORMITY

Fulfil Appendix VII of the Medical Device Directive 93/42/EEC regarding medical products.

We, the company HERDEGEN SAS, 7 Rue Eugène Freyssinet 77500 Chelles, FRANCE, certify that the following products:

GEL SEAT CUSHIONS

GEL cushions	Ref	410 81* or 410 82* or 410 83*
GEL 2D cushions	Ref	410 86*
GEL PERCE cushion	Ref	410 871
GEL AIR 2D cushions	Ref	410 91* or 410 92* or 410 93* or 410 95*
BULGEL cushions	Ref	410 90*

FOAM SEAT CUSHIONS

VISCO'MOUSS' cushions	Ref	410 670 or 410 73* or 410 74* or 410 75* or 410 76*
STABILIS	Ref	410706
K-DOS cushion	Ref	410 707

AIR SEAT CUSHIONS

Protec Air cushions	Ref	41014*
---------------------	-----	--------

FOLDABLE LEG ELEVATOR CUSHIONS

Foldable leg elevator	Ref	410152
-----------------------	-----	--------

POSITIONING CUSHIONS

Half moon cushions	Ref	410 180 or 410 163
Cylinder cushions	Ref	410 181 or 410 161 or 410165
Tube cushions	Ref	410 182 or 410 160
Square cushions	Ref	410 183 or 410 164
Quasi circular cushions	Ref	410 184 or 410 166
Fibro cushion	Ref	410 185

PILLOWS

CARELUX pillow	Ref	420 701 or 420 601
DUOLUX pillow with gel	Ref	420 604, 420 605 or 420 606
DUOLUX foam pillow	Ref	420 704, 420 705 or 420 706
CURVE pillow with gel	Ref	420 602, 420 603 or 420 607
CURVE foam pillow	Ref	420 702, 420 703 or 420 707
Neck support	Ref	420 800, 420 801 or 420 802

Fulfil the complete regulations of:

- The Medical Device Directive 93/42/EEC appendix VII and that these products belong to the class I.
- Directive 2007/47/EC.
- EN ISO 14971 edition 1 (2007) Medical devices – Application of risk management to medical devices.
- EN 12182: Technical aids for disabled persons – General requirements and test methods

This CE declaration is valid for 5 years.

Stutzheim,
February 1st 2020

HERDEGEN SAS
7, rue Eugène Freyssinet
77500 CHELLES
SIRET 508 601 648 000 19 - APE 3250 A
SAS au Capital de 10.681 €

Fabienne Florentin-Chanut