



DECLARATION DE CONFORMITE UE

(Contenu suivant l'annexe IV du MDR 2017/745)

EU DECLARATION OF CONFORMITY

(Content according to Annex IV of MDR 2017/745)

Nous soussignons, société **HERDEGEN (SAS) 6 rue Marc Séguin 77500 Chelles, FRANCE**, fabricant de dispositifs médicaux enregistré sous le numéro unique **FR-MF-000002425** assurons et déclarons que les dispositifs médicaux de **classe I** en vertu des règles de classification n° 1 et/ou 13 de l'annexe VIII du Règlement (UE) 2017/745, dont la liste est annexée, satisfont aux exigences générales en matière de sécurité et de performance du Règlement (UE) 2017/745 (annexe I), aux exigences documentaires techniques (annexes II et III du Règlement (UE) 2017/745) et aux dispositions de la 5^{ième} partie du livre II, titre I du code de la santé Publique qui leur sont applicables.

We, the undersigned, **HERDEGEN (SAS) 6 rue Marc Séguin 77500 Chelles, FRANCE**, manufacturer of medical devices registered under the unique number **FR-MF-000002425** assure and declare that the medical devices of **class I** under the classification rules n° 1 and/or 13 of Annex VIII of Regulation (EU) 2017/745, the list of which is attached, meet the general safety and performance requirements of Regulation (EU) 2017/745 (Annex I), the technical documentation requirements (Annexes II and III of Regulation (EU) 2017/745) and the provisions of Part 5 of Book II, Title I of the Public Health Code that apply to them.

En tant que fabricant de dispositifs médicaux, cette déclaration est établie sous notre seule responsabilité.
As a manufacturer of medical devices, this declaration is established under our sole responsibility.

Cette déclaration couvre les dispositifs mentionnés ci-après, depuis la date de leur mise sur le marché jusqu'à leur date de retrait.

This declaration covers the devices mentioned below, from the date they were placed on the market until their withdrawal date.

Fait à Chelles, le 04/09/2023, pour servir et valoir ce que de droit,
Done in Chelles, on 04th September 2023, to serve and be worth what is right,

LEVAUX Philippe, Directeur Général - General Manager

Liste des dispositifs concernés :
Lista dei dispositivi in questione:

HERDEGEN SAS
6 Rue Marc Seguin
77500 - CHELLES
SIREN 508 601 648 - APE 3250A
SAS au capital de 10682 euros



| Réf | Désignation | Designation | BASIC-UDI-DI |
|-----------------|---|--|-------------------------|
| REF | TRANSFERT | TRANSFER | |
| 410172 | Drap de Glisse Slid Plus 190X75 Cm | Slid plus sliding sheet 190x75cm | 37011277410172FN |
| 41017* | Drap de Glisse Slid Eazy | Slid eazy sliding sheet | 3701127741017SF |
| 41019* | Drap de Glisse Slid | Slid sliding sheet | 3701127741019SK |
| 430916 | Plateforme Levage Et Transfert Turnax | Turnax Transfer Platform | 37011277430916HA |
| 43091* | Ceinture de Transfert Transac | Transac transfer belt | 3701127743091T9 |
| 430921 | Plateforme de ransfert Aéro Move | Aero Move Transfer Platform | 37011277430921H3 |
| 430922 | Plateforme de transfert Easy Move | Easy Move Transfer Platform | 37011277430922H5 |
| 430917 | Sangle pour plateformes de transfert Movy | Universal Belt for Transfer Platforms Movy | 37011277430917HC |
| 430919 | Sangle pour plateformes de transfert Movy Glide | Sliding Belt for Transfer Platforms Movy Glide | 37011277430919HG |
| 430923 | Sangle pour plateformes de transfert Movy Plus | Double Belt for Transfer Platforms Movy Plus | 37011277430923H7 |
| 430924 | Disque Rotatif Turn'Up | Turn'Up rotating transfer disc | 37011277430924H9 |
| Réf | Désignation | Designation | BASIC-UDI-DI |
| Ref | CANNES & CANNES ANGLAISES | STICKS & ELBOW CRUTCHES | |
| 2009** - 2069** | Cannes anglaises Advance | Elbow crutch Advance | 37011277AdvanceDD |
| 2000** - 2020** | Cannes anglaises 130kg Evolution-Fun | Elbow crutch Evolution-Fun | 37011277Evolution_FunFQ |
| 20011* | Cannes anglaises 130kg Evolution tube couleur | Elbow crutch Evolution with coloured pipe | 3701127720012R8 |
| 200700 | Canne anglaises Progress I | Elbow crutch Progress I | 37011277200700EN |
| 201700 | Canne anglaises Progress II | Elbow crutch Progress II | 37011277201700EV |
| 20052* | Cannes anglaises Tiki | Elbow crutch Tiki | 37011277TikiTZ |
| 2203** | Cannes Tripode Triplo | Triplo tripod stick | 37011277Tripod_Triplo8X |
| 100322 | Canne T Derby | Derby stick beechwood | 37011277100322DX |
| 100302 | Canne Maginot Tout Bois | Fritz stick beechwood | 37011277100302DR |
| 100022 | Canne Châtaignier Foncée Boutée | Crook chestnut wood stick | 37011277100322DX |
| 250700 | Canne Maginot | Fritz adjustable stick | 37011277250700GD |
| 250800 | Canne Maginot Bronze | Fritz old bronze stick | 37011277250800GJ |
| 2556** | Canne Derby Fashion pliante | Fashion folding stick | 3701127725560TF |
| 2558** | Canne Derby Fashion non Pliante | Fashion stick non foldable | 3701127725580TM |
| 25061* | Canne Advance bi-matière pliante | Advance "T" foldable Stick | 3701127725060SN |
| 25081* | Canne T Advance bi-matière | Advance "T" Stick non foldable | 3701127725080SU |
| 250280 | Canne Maginot 90 cm pliante | Fritz foldable stick 90cm with case | 37011277250280SA |
| 250281 | Canne Derby Pliante Réglable Étui | Derby foldable and adjustable stick with case | 37011277250281GE |
| 255827 | Canne derby pliante Black diamond | Soft Touch stick Black Diamond foldable | 37011277250287GS |
| 24360* | Canne anatomique alu anodisé gris | Anatomic stick | 3701127724360SW |
| 24362* | Canne Anatomique Alu Époxy Marron | Anatomic stick brown | 3701127724362T2 |
| 24363* | Canne Palmaire Pliante Flower Black And White | Anatomic stick foldable flower black & white | 3701127724363T4 |
| 24364* | Canne Palmaire | Anatomic stick | 3701127724364T6 |
| 243645 | Canne Palmaire Droite imitation Carbone | Anatomic walking stick carbon style Right | 37011277243645H8 |

| Réf | Désignation | Designation | BASIC-UDI-DI |
|------------------------------|---|--|---------------------------|
| Ref | CANNES & CANNES ANGLAISES | STICKS & ELBOW CRUTCHES | |
| 243646 | Canne Palmaire Gauche imitation Carbone | Anatomic walking stick carbon style Left | 37011277243646HA |
| 250500 | Canne Blanche Pliante Poignée T Casper | Casper foldable white stick | 37011277250500G3 |
| 2509** | Canne Blanche Pliante Mailloche | Knob foldable white stick | 3701127725090SX |
| 25072* | Canne Twist And Light | Twist light adjustable stick | 3701127725072SV |
| 116001 | Canne Trépied noire Trisit | Trisit Aluminium tripod seat stick black | 37011277116001EV |
| 116801 | Canne Quatro Noire | Quatro Black stick | 37011277116801G5 |
| 260001 | Kit Cannes Fashion | Set of Fashion walking sticks | 37011277260001FP |
| 260003 | Pack Cannes Luxe | Set of "de Luxe" walking sticks | 37011277260003FT |
| Réf | Désignation | Designation | BASIC-UDI-DI |
| Ref | LEADUP ET COLEADUP | LEADUP & COLEADUP | |
| 7001** | Fauteuil Lead up vérin à gaz palette | Transfer chair Lead up with gaz spring | 37011277leadupgazPJ |
| 7002** | Fauteuil Lead up électrique palette | Transfer chair Lead up with actuator | 37011277leadupelecZT |
| 7003** | Fauteuil Coleadup électrique | Transfer chair Colead up with gaz spring | 37011277ColeadupelecDM |
| 7004** | Fauteuil Coleadup à gaz | Transfer chair Colead up with actuator | 37011277ColeadupgazQB |
| EMBOUTS | | FERRULES | BASIC-UDI-DI |
| 910*** | Embout Pour Canne bois | Rubber tip interior for wooden sticks | 37011277910*VentousesVM |
| 917030 | Porte Canne Pour Rollators | Stick holder for rollators | 37011277917030JK |
| 920000 | Embout Triade | Triade rubber tip | 37011277920000H4 |
| 920014 | Ventouse Diam Intérieur 17mm | Rubber tip inside diameter 17mm | 3701127792001*emboutsWZ |
| 920*** | Embout De Cannes anglaises | Standard tip for elbow crutch | 37011277920***emboutsLJ |
| 920214 | Ventouse Diam Intérieur 19 Mm Grise | Rubber tip interior diameter 22mm grey | 37011277920214HR |
| 92051* | Embout Gris Diam 16/35 Mm Canne T Métal | Grey tip 16mm basis 35mm | 3701127792051*embouts3M |
| 920600 | Ventouse Pour Déambulateur | Rubber tip for walking frame | 37011277926**emboutsV6 |
| CADRES DE MARCHE & ROLLATORS | | WALKING FRAMES & ROLLATORS | BASIC-UDI-DI |
| 221000-221100 | Déambulateur MOVIGO | MOVIGO walking frame | 37011277221_MovigoCM |
| 221099 | Jeu de Roulettes pour déambulateur 221100 | Wheels for walking fram ref 221100 | 37011277221099FV |
| 243880 | Rollator Shopiroll | Shopiroll Rollator | 37011277243880HL |
| 2439** | Modelito Wp Home | Modelito WP Home | 37011224390HA |
| 24301* | Rollator Simply Neo | Rollator Simply Neo | 37011277243_Simply_NeoKN |
| CANNES EN BOIS | | WOODEN WALKING STICKS | BASIC-UDI-DI |
| 100102 | Canne Courbe Noire | Crook stick with Black handle | 37011277100102DF |
| 100301 | Canne Maginot Tout Bois | T walking stick | 37011277100301DP |
| 102000 | Canne Béquillon Noir | Fritz stick w/ Black handle on beechwood | 37011277102000DL |
| LITS MEDICALISES | | MEDICAL BEDS | BASIC-UDI-DI |
| 46**** | Lit 2F Ampliplus | Ampliplus bed 2F | 3701127746_Ampliplus_2F62 |
| 47**** | Lit 3F Ampliplus | Ampliplus bed 3F | 3701127746_Ampliplus_3F65 |
| 46***V | Lit 2F Ampliplus avec verrouillage | Ampliplus bed 2F with central locking | 3701127746_Ampliplus2Fv49 |
| 47***V | Lit 3F Ampliplus avec verrouillage | Ampliplus bed 3F with central locking | 3701127746_Ampliplus3Fv4E |

| | TABLES | BED TABLES | BASIC-UDI-DI |
|---|--|---|---------------------------|
| 421*** | Table de lit Diffusion | Diffusion Bed table | 37011277421_DiffusionH5 |
| 421*** | Table de lit Diffusion + tablette | Diffusion Bed table + side table | 37011277421_Diffusion_TZW |
| 42170* | Tablette latérale | Side plate | 370112774217_tabletteXK |
| 4228** | Table Pont Easybridge (Lit 90 Cm) | Easy Bridge Bed table (bed 90cm) | 370112774228_EasybridgeNX |
| | ACCESSOIRES DE LIT | BEDROOM: ACCESSORIES | BASIC-UDI-DI |
| 430930 | Poignée de sortie de lit Protect Ultra | Protect Ultra Bedrail | 3701124309303B |
| 430918 | Poignée de sortie de lit Protect | Protect universal bedrail | 3701124309183M |
| 430920 | Poignée de sortie de lit Protect Plus | Protect Plus universal under mattress bedrail | 37011277430920GZ |
| 43091* | Potence Pliante ou fixe Macaréna | Lifting pole "Macarena" foldable or not | 37011277MacarenaZH |
| 430002 | Potence d'Angle de lit Ampliplus | Lifting pole for Ampliplus bed | 37011277430002FJ |
| 430*** | Barrière Bois | Wooden side rails | 3701127743015barriereB4P |
| 430*** | Barrière lit Pliante Droite/gauche Epoxy Beige | Metal side rail right/left | 37011277Barriere_metalKX |
| 430*** | 1/2 Barrière Droite/gauche | 1/2 Side rail right/left | 37011277Demi_BarriereFN |
| 4304** | Barrière Droite/Gauche Avec Étaux | Side rails with clamps, right/left | 37011277Barriere_etauxL5 |
| 43041* | Protection Barrières de lit | Full side rail cover | 3701127743041_coversSU |
| 4306** | Panneaux MDF | Board MDF | 37011277Panneaux_MDFHM |
| 4307** | Panneaux Main Courante Hêtre | Board wooden | 37011277Panneaux_HMCHH |
| 430*** | Panneaux Design | Boards Design | 37011277Panneaux_Design5S |
| 430800 | Porte Sérum 4 Crochets Chromés | IV Stand chromed | 3701127743081_IVstandCD |
| 430905 | Triangle Complet Pour Potence | Handle for pole | 37011277430905H5 |
| 420280 | Appui Dos Sangle Bleue Relaxo | Relaxo backrest with Blue strap | 37011277420280G5 |
| 42030* | Arceaux de lit Rainbow I et II | Rainbow I & II bed cradles | 370112774203_arceauxGC |
| | POSITIONNEMENT | POSITIONNING CUSHIONS | BASIC-UDI-DI |
| 410170 | Inclinez Bébé 64x35x29 Cm | Reclining cushion for baby 64*35*29cm | 37011277410170FJ |
| 410200 | Coiffe Anallergique 190*90*20cm | Dermalon cover 190*90*20cm | 37011277410200F2 |
| 410707 | K-Dos 2 housses 3D | K-DOS backsupport with two 3D covers | 37011277410707G9 |
| 680008 | Protège talon (paire) | Heel protector standard (per pair) | 37011277680008JF |
| 680010 | Talonia Visco | Talonia Visco Heel protector | 37011277Talonia_viscoVT |
| 680011 | Talonia Fibro | Talonia Fibro Heel protector with fibres | 37011277680011J4 |
| | COUSSINS | CUSHIONS | BASIC-UDI-DI |
| 41068* - 41070* 41071* - 41072* 41074* - 41075* 41701* | Coussins Visco' Mouss | Visco' Mouss cushion | 37011277ViscomoussZV |
| 41077* - 41078* | Coussins Visco' Mouss avec butée | Visco' Mouss cushion with pommel | 37011277Viscomouss_BH4 |
| 41080* - 41081* 41082* - 41083* 41084* - 41085* | Coussins Gel | Gel cushions | 37011277Coussins_Gel5X |
| 41096* - 41097* 41098* | Gel fluide | Gel fluide cushion | 37011277Gel_FluideRR |
| 41086* - 41087* | Coussins Gel 2D | Gel 2D cushions | 37011277Coussins_Gel2DA5 |

| | COUSSINS | CUSHIONS | BASIC-UDI-DI |
|--|--|---|---------------------------|
| 41090* - 41091* 41092* - 41093* 41094* - 41095* | Coussins Gel Air 2D | Gel Air 2D cushions | 37011277CoussinGelAir2D8M |
| 410*** | Coussins Gel Air 3D | Gel Air 3D cushions | 37011277CoussinGelAir3D8Q |
| 410903 - 410904 410905 - 410906 410907 - 410908 410909 - 410910 | Bulgel | Bulgel | 37011277Coussin_BulgelB5 |
| 410670 | Coussin Wavy plus | Wavy Plus viscoelastic foam cushion | 37011277Coussin_Wavy48 |
| 410955 | Coussin Wavy plus coussin mousse & gel | Wavy Plus viscoelastic foam & gel cushion | 37011277Wavy_plus_gelQ4 |
| | COUSSINS | CUSHIONS | BASIC-UDI-DI |
| 410151 | Coussin rond percé Rondo | Rondo foam ring cushion | 37011277410151FE |
| 410851 | Coussin rond percé Rondo Plus | Rondo Plus foam ring cushion | 37011277410851GH |
| 420936 | Coussin triangulaire Coxy Care | Coxy Care triangular cushion | 37011277420936H5 |
| 41010* - 41011* 41012* - 41013* | Coussin mousse 25kg/m3 | Foam Cushion 25kg/m3 | 37011277Coussin_25kgm3EC |
| 410152 | Rehausse jambe Trilux | Trilux leg elevator | 37011277410152FG |
| 410150 - 410153 410154 | Coussin gaufrier Cube | Cube foam waffle cushion | 37011277Coussin_gaufreKU |
| | MATELAS | MATTRESSES | BASIC-UDI-DI |
| 41004* | Matelas gaufrier Sleepy | Waffle mattress Sleepy | 37011277Mat_GaufrierYZ |
| 41005** | Matelas Maxi Aero | Maxi Aero mattress | 37011277Mat_Maxi_AeroMW |
| 410060* - 410069* 41008* | Matelas classe II visco Maxi | Maxi antidecubitus mattress | 37011277Mat_MaxiZV |
| 410061* - 410062 410063 | Matelas classe II visco Topi | Topi antidecubitus mattress | 37011277Mat_Topi4X |
| 410090* - 410091* | Matelas Easy Visco | Easy visco antidecubitus mattress | 37011277Mat_Easy_ViscoSN |
| 41100* | Matelas clinique HR 38kg Access Plus | Access Plus mattress HR 38kg | 37011277Mat_HR_38kgE7 |
| 41200* | Matelas clinique 27kg Access | Access mattress 27kg | 37011277Mat_Clin_27kg4U |
| | HOUSSES ET COIFFES | COVERS | BASIC-UDI-DI |
| 41030* | Coiffe anallergique | Cover for mattress | 37011277Mat_CoiffeVY |
| 410400 | Housse PVC M1 | PVC cover M1 | 37011277Mat_Housse_PVC6U |
| 410401 | Housse PU | PU cover | 37011277Mat_Housse_PU5P |
| 410100 | Alèze dermalon | Dermalon cover | 37011277Mat_Aleze_DermaSS |
| | CHAISES PERCEES | COMMODE CHAIRS | BASIC-UDI-DI |
| 305011 - 305023 306011 - 306023 | New open | New Open | 37011277NewOpen_Chaise6E |
| 315011 - 315023 316011 - 316023 | New open réglable | New Open adjustable | 37011277NewOpen_RegNV |
| 309011 - 309023 | New Open en kit | New Open as a kit | 37011277Openkit_ChaiseU5 |
| 3040** - 3045** 3047** - 3048** | Best up pliant | Best Up foldable | 37011277Bestup_plianteD5 |
| 3047** - 3048** | Best up roulettes acc esc | Best Up on castors | 37011277Bestup_rouletteA2 |
| 32002* - 32012* | New Club | New Club | 37011277Newclub_ChaiseMP |

| | CHAISES PERCEES | COMMODE CHAIRS | BASIC-UDI-DI |
|--------|---|---|---------------------------|
| 36462* | Best up XL | Best Up XL | 37011277Bestup_XL8Y |
| 380002 | Blue Steel 3 en 1 | Blue steel 3 in 1 | 37011277380002GU |
| 380004 | Alustyle 4 en 1 | Alustyle 4 in 1 | 37011277380004GY |
| | REHAUSSES WC | TOILET RAISERS | BASIC-UDI-DI |
| 50000* | ClipUp | ClipUp | 37011277Clipup_Rehausse88 |
| 5002** | Contact Plus neo | Contact Plus neo | 37011277Contact_NeoSY |
| 5003** | Contact Plus neo avec couvercle | Contact Plus néo with lid | 37011277Contact_Neo_CouT4 |
| 5004** | Clipper I-II-III | Clipper I-II-III | 37011277Clipper1-2-3A3 |
| 500420 | Clipper IV | Clipper IV | 370112775Clipper4/53C |
| 500421 | Clipper V | Clipper V | 370112775Clipper4/53C |
| 500430 | Clipper VI | Clipper VI | 370112775Clipper6/73S |
| 500431 | Clipper VII | Clipper VII | 370112775Clipper6/73S |
| | BAIN, DOUCHE ET TOILETTE | BATH, SHOWER AND TOILET | BASIC-UDI-DI |
| 54022* | Siège de Bain pivotant Atlantis IV | Rotating bath seat Atlantis IV | 3701127754022*AtlantisJP |
| 540300 | Siège de douche à roulette Atlantis | ATLANTIS Wheeled shower seat | 37011277540300GM |
| 54033* | Chaise de douche & toilette Aq-Tica | AQ-TICA Shower-commode chair | 37011277Aq-TicaQR |
| 540381 | Siège de douche & toilette à roulette Obana | Obana mobile shower & commode chair | 37011277540381HF |
| 540382 | Chaise de douche Aquareha | Aquareha tilting shower chair | 37011277540382HH |
| 550800 | Planche de bain Obana | Bath board Obana 200 kg | 37011277550800HR |
| 550805 | Poignée de baignoire Obafix | Bathtub handle Obafix | 37011277550805J3 |
| 550806 | Acces-O-Bain | Bath access kit ACCES-O-BAIN | 37011277550805J3 |
| 570806 | Cadre de Sécurité WC Cadrofix | CADROFIX Toilet safety frame with 4 legs | 37011277570806JT |
| 570807 | Cadre de WC Classic | Toilet support rail with armrests CLASSIC | 37011277570807JV |
| 580500 | Bidet pour WC Vasco | Bidet for toilet bowl VASCO | 37011277580500JB |