

DECLARATION DE CONFORMITE UE

Conformément à l'annexe IV du règlement (UE) 2017/745

EU DECLARATION OF CONFORMITY, According to Annex IV of Regulation (EU) 2017/745

Fabricant <i>Manufacturer</i>	
Raison sociale <i>Company name</i>	Hopper
Adresse <i>Address</i>	8 Avenue Pierre Gilles de Gennes 81000 Albi FRANCE
Numéro d'enregistrement unique (EUDAMED) <i>Unique registration numer (EUDAMED)</i>	FR-MF-000024280

Hopper, fabricant des dispositifs médicaux faisant l'objet de cette déclaration, atteste sous sa seule responsabilité que :

- Les produits faisant l'objet de cette déclaration sont en conformité avec les exigences du Règlement (UE) 2017/745

Hopper, the manufacturer of the medical devices that are the subject of this declaration, certifies under its sole responsibility that:

- The products that are the subject of this declaration comply with the requirements of Regulation (EU) 2017/745.

Référence <i>Reference</i>	Dénomination commerciale <i>Commercial name</i>	Basic IUD-ID	IUD-ID / GTIN
HP01TXS-A	Outsider by Hopper TXS-A	3770027689HP012T	03770027689263
HP01TS-A	Outsider by Hopper TS-A	3770027689HP012T	03770027689256
HP01TM-A	Outsider by Hopper TM-A	3770027689HP012T	03770027689249
HP01TL-A	Outsider by Hopper TL-A	3770027689HP012T	03770027689232
HP01TXL-A	Outsider by Hopper TXL-A	3770027689HP012T	03770027689270
HP01TXS-B	Outsider by Hopper TXS-B	3770027689HP012T	03770027689225
HP01TS-B	Outsider by Hopper TS-B	3770027689HP012T	03770027689218
HP01TM-B	Outsider by Hopper TM-B	3770027689HP012T	03770027689201
HP01TL-B	Outsider by Hopper TL-B	3770027689HP012T	03770027689195
HP01TXL-B	Outsider by Hopper TXL-B	3770027689HP012T	03770027689188
HP01TXXL-B	Outsider by Hopper TXXL-B	3770027689HP012T	03770027689171
HM02-1-24	Outsider Footshell multiaxial upper and heel pads Sh1 <95kg Size 24	3770027689HP012T	03770027689430
HM02-1-25	Outsider Footshell multiaxial upper and heel pads Sh1 <95kg Size 25	3770027689HP012T	03770027689423

HM02-1-26	Outsider Footshell multiaxial upper and heel pads Sh1 <95kg Size 26	3770027689HP012T	03770027689416
HM02-1-27	Outsider Footshell multiaxial upper and heel pads Sh1 <95kg Size 27	3770027689HP012T	03770027689409
HM02-1-28	Outsider Footshell multiaxial upper and heel pads Sh1 <95kg Size 28	3770027689HP012T	03770027689393
HM02-1-29	Outsider Footshell multiaxial upper and heel pads Sh1 <95kg Size 29	3770027689HP012T	03770027689386
HM02-1-30	Outsider Footshell multiaxial upper and heel pads Sh1 <95kg Size 30	3770027689HP012T	03770027689379
HM02-2-24	Outsider Footshell multiaxial upper and heel pads Sh2 >95kg Size 24	3770027689HP012T	03770027689362
HM02-2-25	Outsider Footshell multiaxial upper and heel pads Sh2 >95kg Size 25	3770027689HP012T	03770027689355
HM02-2-26	Outsider Footshell multiaxial upper and heel pads Sh2 >95kg Size 26	3770027689HP012T	03770027689348
HM02-2-27	Outsider Footshell multiaxial upper and heel pads Sh2 >95kg Size 27	3770027689HP012T	03770027689331
HM02-2-28	Outsider Footshell multiaxial upper and heel pads Sh2 >95kg Size 28	3770027689HP012T	03770027689324
HM02-2-29	Outsider Footshell multiaxial upper and heel pads Sh2 >95kg Size 29	3770027689HP012T	03770027689317
HM02-2-30	Outsider Footshell multiaxial upper and heel pads Sh2 >95kg Size 30	3770027689HP012T	03770027689300

Destination <i>Intended use</i>	Ces produits sont des dispositifs médicaux visant à remplacer la fonction de cheville et de pied chez les personnes amputées des membres inférieurs souhaitant réaliser une activité physique de course à pied ou de marche. <i>These products are medical devices intended to replace ankle and foot function in lower limb amputees who wish to engage in the physical activity of walking or running.</i>
Classe de risque <i>Risk class</i>	Ces produits appartiennent à la classe I, conformément aux règles établies à l'annexe VIII. <i>These products belong to Class I according to the rules laid down in Annex VIII.</i>
Lieu, date de délivrance de la déclaration <i>Place and date of the declaration</i>	Albi, le 03/09/2026
Nom et fonction du signataire <i>Name and position of signatory</i>	Premaud Victor, Directeur-Général SAS Hopper
Signature	