

EU Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
Turbomed Orthotic Inc.	240 de Sydney (ste 101), St-Augustin-De-Desmaures, QC, G3A 0P2, Canada	CA-MF-000032108

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Phone/e-mail
OKO SOLUTION	157 Avenue Gaston Imbert Rousset Parc II 13790 Rousset, France	FR-AR-000006781	+33.4.88.19.60.10

PRODUCT IDENTIFICATION	
Product Name	Code/Catalog Number
Xtern AFO semi-assembled kit, all 4 sizes Xtern AT-X AFO Clinical Trial Adjustable orthotic, all 4 sizes Xtern AFO Options Xtern AFO Soft Parts Replacement Xtern AFO Parts	See Appendix A
Intended Purpose	Basic UDI-DI
Ankle foot orthotic for patients suffering from drop foot disease	See Appendix A

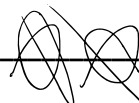
RISK CLASS FOR DEVICES		
Device Classification	Common Specifications/standards	
Classe :	1	Refer to General Safety and Performance Checklist
Rule :	1	

Turbomed Orthotics Inc. declares that the above-mentioned products meet the provision of the following EU legislation: **Medical Devices Regulation (UE) 2017/745**

Company Representative : Stephane Savard

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on this behalf by a third party.

Title: President and General Manager **Signature:** _____



Date: 2024-02-14

Place: Quebec, Canada



Company Representative : Stephane Savard
 Title : President and General Manager
 Place : Quebec , Canada
 Date : 2024-02-14

Version 2.9

Appendix A – Product Listing/Schedule

CATALOGUE FAMILY PRODUCT CODE (SKU)	DEVICE NAME - DESCRIPTION	Basic UDI-DI (GMN) UDI-DI (GTIN)
100100 100100-SA-L 100100-SA-M 100100-SA-S 100100-SA-P	XTERN CLASSIC FOOT DROP ORTHOTIC XTERN CLASSIC FOOT DROP ORTHOTIC, SIZE LARGE XTERN CLASSIC FOOT DROP ORTHOTIC, SIZE MEDIUM XTERN CLASSIC FOOT DROP ORTHOTIC, SIZE SMALL XTERN CLASSIC FOOT DROP ORTHOTIC, SIZE PEDIATRIC	62055328100100GQ 620553280881 620553280898 620553280904 620553280911
101100 101100-SA-L 101100-SA-M 101100-SA-S	XTERN SUMMIT FOOT DROP ORTHOTIC XTERN SUMMIT FOOT DROP ORTHOTIC, SIZE LARGE XTERN SUMMIT FOOT DROP ORTHOTIC, SIZE MEDIUM XTERN SUMMIT FOOT DROP ORTHOTIC, SIZE SMALL	62055328101100GX 620553281352 620553281369 620553281376
102100 102100-SA-L 102100-SA-M 102100-SA-S	XTERN FRONTIER ANTERIOR FOOT DROP ORTHOTIC XTERN FRONTIER ANTERIOR FOOT DROP ORTHOTIC, SIZE LARGE XTERN FRONTIER ANTERIOR FOOT DROP ORTHOTIC, SIZE MEDIUM XTERN FRONTIER ANTERIOR FOOT DROP ORTHOTIC, SIZE SMALL	62055328102100H6 620553281314 620553281321 620553281338
109100 109100-TK-SML 109100-AT-L 109100-AT-M 109100-AT-S 109100-AT-P	AT-X ASSESSMENT TOOL (CLINICAL TRIAL ADJUSTABLE ORTHOTIC) AT-X ASSESSMENT TOOL TRIAL KIT (SMALL MEDIUM LARGE) AT-X ASSESSMENT TOOL SIZE LARGE AT-X ASSESSMENT TOOL SIZE MEDIUM AT-X ASSESSMENT TOOL SIZE SMALL AT-X ASSESSMENT TOOL SIZE PEDIATRIC	62055328109100JP 620553280874 620553281000 620553280966 620553280973 620553280980
500100 500100-AST-SML 500201-EXT-SML 500250-HBP-SML	XTERN OPTIONS ANKLE STABILISATION STRAP, SIZE SMALL-MEDIUM-LARGE EXTENSION STOPPER KIT, SIZE SMALL MEDIUM-LARGE HEEL BUMPER KIT SMALL-MEDIUM-LARGE	62055328500100JC 620553280560 620553281178 620553281406
500300 500302-K00-SML 500301-K00-P 501302-K00-ML 501302-K00-S 502400-K00-SML	XTERN SOFT PARTS - REPLACEMENT PARTS CALF PAD & STRAP KIT, SIZE SMALL-MEDIUM-LARGE CALF PAD & STRAP KIT, SIZE PEDIATRIC MOLDED CALF PAD & STRAP KIT, SIZE MEDIUM-LARGE MOLDED CALF PAD & STRAP KIT, SIZE SMALL MOLD.SHIN PAD,MAGNET STRAP KIT,SMALL-MED.-LARGE	62055328500300JN 620553281390 620553280959 620553281291 620553281383 620553281307
200000 200000-Y10-ML 200000-U00-ML 200000-L00-ML 200000-C00-ML 200000-W10-L 200000-W10-M 200000-Y10-S 200000-U00-S 200000-L00-S 200000-C00-S 200000-W10-S 200000-Y00-P 200000-U00-P 200000-W00-P 200000-L00-P 200000-C00-P 200000-B10-P 201000-Y00-L 201000-Y00-M 201000-Y00-S 201000-U00-L 201000-U00-M 201000-U00-S 201000-R00-ML 201000-R00-S 201000-C00-ML 201000-C00-S 202000-F00-ML (R-L) 202000-F00-S (R-L) 202000-S00-M 202000-S00-S	XTERN FOOT DROP ORTHOTICS - PLASTIC PARTS REPLACEMENT MAIN POSTERIOR SECTION «Y» SHAPE, SIZE MEDIUM LARGE FRONT SHOE SECTION «U» SHAPE, SIZE MEDIUM-LARGE LACE CLIP ATTACHMENT, SIZE MEDIUM-LARGE CALF SECTION, SIZE MEDIUM-LARGE REAR HEEL SECTION SUPPORT, SIZE LARGE (BLOC INTEGRATED) REAR HEEL SECTION SUPPORT, SIZE MEDIUM (BLOC INTEGRATED) MAIN POSTERIOR SECTION «Y» SHAPE, SIZE SMALL FRONT SHOE SECTION «U» SHAPE, SIZE SMALL LACE CLIP ATTACHMENT, SIZE SMALL (aka FS3000-L00-S) CALF SECTION, SIZE SMALL REAR HEEL SECTION SUPPORT, SIZE SMALL (BLOC INTEGRATED) MAIN POSTERIOR SECTION «Y» SHAPE, SIZE PEDIATRIC FRONT SHOE SECTION «U» SHAPE, SIZE PEDIATRIC REAR HEEL SECTION SUPPORT, SIZE PEDIATRIC LACE CLIP ATTACHMENT, SIZE PEDIATRIC CALF SECTION, SIZE PEDIATRIC JUNCTION BLOC ADJUSTABLE, SIZE PEDIATRIC MAIN SECTION «Y» SIZE LARGE MAIN SECTION «Y» SIZE MEDIUM MAIN SECTION «Y» SIZE SMALL FRONT «U» SIZE LARGE FRONT «U» SIZE MEDIUM FRONT «U» SIZE SMALL CARBON FIBER RODS 300 L. MED.LARGE CARBON FIBER RODS 250 L. SMALL CALF SECTION SIZE MED.LARGE CALF SECTION SIZE SMALL FLEX ARTICUL.RIGHT-LEFT, SIZE MED. LARGE FLEX ARTICUL.RIGHT-LEFT, SIZE SMALL SHIN ARCH SECTION, SIZE MEDIUM SHIN ARCH SECTION, SIZE SMALL	62055328200000GY 620553281277 620553280720 620553280300 620553280751 620553281130 620553281147 620553281284 620553280782 620553280249 620553280805 620553281154 620553280829 620553280836 620553280843 620553280164 620553280850 620553281086 620553281420 620553281437 620553281444 620553281451 620553281468 620553281475 620553281505 620553281383 620553281482 620553281499 620553281246 620553281253 620553281260 620553281413