

EC-Conformity Declaration

(according to Appendix IX of the Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council)

We,
 Bauerfeind AG
 Triebeser Str. 16
 D-07937 Zeulenroda-Triebes
 SRN: DE-MF 000007543

declare in exclusive accountability, that our products:

Name	Intended Use	Basis-UDI-DI
ErgoPad® Sensitive	Orthopedic orthoses are functional orthoses for the feet and are suitable for use in treating and preventing foot complaints.	4046445EPSe0000000RN
ErgoPad®soft Diabetes	Orthopedic orthoses are functional orthoses for the feet and are suitable for use in treating and preventing foot complaints.	4046445EPsoDB00000047
ErgoPad® weightflex 2	Orthopedic orthosis that is suitable for the use in treating and preventing foot complaints. It supports the natural gait pattern to its flexible/ medium/ stable arch support.	4046445EPwf2000000HP
ErgoPad® redux heel 2	Orthopedic orthosis for the feet that is suitable for use in treating and preventing foot conditions.	4046445EPrh2000000FA
ErgoPad® ball & racket	Supportive foot orthosis that makes sports shoes more comfortable to wear and helps stabilize the movement of the hindfoot during athletic activities. Suitable for: Racket and other sports, such as volleyball, handball, basketball, tennis, badminton, squash, golf, football (depending on footwear).	4046445EPbr00000008N
ErgoPad® run & walk	Supportive foot orthosis that makes sports shoes more comfortable to wear and helps stabilize the movement of the hindfoot during athletic activities. Suitable for: Running, hiking, walking.	4046445EPrw0000000P5

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ErgoPad® ski & skate	Supportive foot orthosis that makes sports shoes more comfortable to wear and helps stabilize the movement of the hindfoot during athletic activities. Suitable for: downhill skiing, cross-country skiing, ice hockey, inline skating.	4046445EPss0000000MG
GloboTec® Junior	Orthopedic shell foot orthosis suitable for treating foot deformities in children and adolescents until their body growth is completed.	4046445GTJ00000000UR
GloboTec® comfort business	Orthopedic orthoses suitable for use in treating and preventing foot complaints.	4046445SES00000000Z9
GloboTec® comfort sports	Orthopedic orthoses suitable for use in treating and preventing foot complaints.	4046445GPcs0000000BW
ErgoPad® Soft	Orthopedic orthosis that is suitable for the use in treating and preventing foot complaints. The viscoelastic soft foam cushions the foot and provides relief through redistribution of pressure.	4046445EPso0000000K4
Visco Balance®	Viscoelastic heel cushion for compensating leg lengths differences of 3, 5 and 10 mm. Thanks to the heel wedge, the product also serves to relieve the Achilles tendon.	4046445ViB00000000L5
Visco Heel K®	Viscoelastic heel cushion. It is used as a supination or pronation cushion. ViscoHeel K can be used for the targeted correction of varus or valgus misalignments of the heel bone as well as leg axis misalignment.	4046445ViK00000000SL
Visco Heel®	Viscoelastic heel cushion. It provides shock absorption and relief during load peaks. ViscoHeel can also be used for redistribution of pressure and for pain reduction when treating pathologies in the heel and hindfoot area.	4046445ViH00000000QF
Visco Ped®	Viscoelastic foot orthosis for providing pressure relief in the forefoot, midfoot and heel area as well as for the gentle correction of static or dynamic misalignments of the foot's skeleton.	4046445ViP00000000W7
Visco Ped® S	Viscoelastic foot orthosis for providing relief in the forefoot, midfoot and heel area as well as for the gentle correction of static or dynamic misalignments of the foot's skeleton.	4046445ViPS00000000JG

Visco Spot®	Viscoelastic heel cushion. It provides shock absorption and relief during load peaks. ViscoSpot can also be used for redistribution of pressure and for pain reduction when treating pathologies in the heel and hindfoot areas.	4046445ViS00000000YC
GloboPed® Mobil	Orthosis for providing the heel area with targeted relief.	4046445GPFM00000006Y
GloboPed® Postop	Orthosis for providing the forefoot and anterior metatarsal area with targeted relief.	4046445GPVA0000000BC
TRlactive OA	Orthopedic foot orthosis for providing support as well as relief in cases of foot axis misalignments and osteoarthritis of the knee.	4046445TRIOA0000000Z8

comply with the General Safety and Performance Requirements according to Annex I of the Medical Device Regulation (EU) 2017/745. Within the conformity evaluation process there has been no participation of a Notified Body.

The products have been classified according to Annex VIII, Chapter III, MDR 2017/745 in risk class I. They correspond to the given provisions of the Regulation (EU) 2017/745 for Medical Devices.

Zeulenroda-Triebes, 31.01.2023



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 Compliance
 Bauerfeind AG



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