

BAUERFEIND AG • TRIEBESER STR. 16 • 07937 ZEULENRODA-TRIEBES

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
VenoTrain® business	Compression stockings for the long-term therapy of phlebological and / or lymphological disorders as well as for the long-term therapy of lipedema	4046445BUS00000000XA
VenoTrain® look	Compression stockings for the long-term therapy of phlebological and / or lymphological disorders as well as for the long-term therapy of lipedema	4046445LOO00000000YN
VenoTrain® cocoon	Compression stockings for the long-term therapy of phlebological and / or lymphological disorders	4046445COC00000000FB
VenoTrain® delight/ VenoTrain® delight T	Compression stockings for the long-term therapy of phlebological and / or lymphological disorders as well as for the long-term therapy of lipedema	4046445DEL00000000DP
VenoTrain® discrétion	Compression stockings for the long-term therapy of phlebological and / or lymphological disorders	4046445DIS00000000NC
VenoTrain® impuls	Compression stockings for the long-term therapy of phlebological and / or lymphological disorders as well as for the long-term therapy of lipedema	4046445IMP00000000UN
VenoTrain® micro	Compression stockings for the long-term therapy of phlebological and / or lymphological disorders as well as for the long-term therapy of lipedema	4046445MIC00000000KK

ANSCHRIFT

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BAUERFEIND.COM

VenoTrain® pure	Compression stockings for the long-term therapy of phlebological and / or lymphological disorders as well as for the long-term therapy of lipedema	4046445VTP00000000FP
VenoTrain® soft	Compression stockings for the long-term therapy of phlebological and / or lymphological disorders as well as for the long-term therapy of lipedema	4046445SOF00000000YY
VenoTrain® soft S	Compression stockings for the long-term therapy of phlebological and / or lymphological disorders	4046445SOFs000000005D
VenoTrain® ulcertec	Compression stockings for the long-term treatment of severe phlebological disorders in the legs	4046445ULC00000000W2
VenoTrain® curafLOW	Compression stockings for the long-term therapy of phlebological and / or lymphological disorders as well as for the long-term therapy of lipedema	4046445CUR000000000XJ
VenoTrain® curafLOW strong	Compression stockings for the long-term therapy of phlebological and / or lymphological disorders as well as for the long-term therapy of lipedema	4046445CURs000000003X
VenoTrain® angioflow	Circular knit compression stocking for longterm treatment of predominantly phlebological illnesses.	4046445ANG000000000FC
VenoTrain® glider	Accessory to a medical device. It makes it easier to put on medical compression stockings for the lower and upper extremities	4046445GLI000000000LS
VenoTrain® glider plus	Accessory to a medical aid. This product makes it easier to put on medical compression stockings for the lower extremities (up to compression class 3)	4046445GLIP000000007A


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, 28th August 2023



Ines Exner
Person Responsible for Regulatory
Compliance
Bauerfeind AG



p.o. Dr. Beatrice Zimmerling
Senior Regulatory Affairs Manager
Bauerfeind AG