



EU DECLARATION OF CONFORMITY

In accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, and repealing Council Directives 90/385/EEC and 93/42/EEC.

Manufacturer name and address:

Diawin s.r.o.
Cermelska cesta 1
04001 Kosice
Slovak Republic

Manufacturer Identification Number (SRN): SK-MF-000048596

Name of the medical device:

Orthopedic footwear for diabetics – Diawin D3 Series

Models of the medical device:

- **Ethereal**, sizes 36–50; widths: medium, wide, extra wide
- **Serene**, sizes 36–50; widths: medium, wide, extra wide
- **Ashline**, sizes 36–50; widths: medium, wide, extra wide
- **Nightcall**, sizes 36–50; widths: medium, wide, extra wide
- **Noir**, sizes 36–50; widths: medium, wide, extra wide
- **Pure**, sizes 36–50; widths: medium, wide, extra wide

As the manufacturer, we declare and guarantee that these medical devices:

- are Class I medical devices according to Rule 1 of Annex VIII of Regulation (EU) 2017/745 on medical devices;
- fulfil the General Safety and Performance Requirements and comply with Regulation (EU) 2017/745 on medical devices.

Conformity assessment procedure applied: Annex II + Annex III of Regulation (EU) 2017/745

Applied standards:

EN ISO 14362-1:2017 (textile), EN ISO 14362-3:2017 (textile), CEN ISO/TS 16179:2012, EN 1122:2001 Method B, ISO 18219-1:2021, ISO 18254-1:2016 (textile), AfPS GS 2019:01 PAK, ISO 16181-1:2021, ISO 16186:2021, DIN EN ISO 14184-1:2011, DIN 54231:2022

These medical devices bear the CE marking.

All documents, including the technical documentation, are kept by the manufacturer.

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

Basic UDI-DI:

Ethereal 85850746FM40U2

Serene 85850746FF45T9

Ashline 85850746FM43U8

Nightcall 85850746FM44UA

Noir 85850746FM41U4

Pure 85850746FM42U6

diawin

Diawin s.r.o.
Cermelská cesta 1
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IČO: 36830712
DIČ DPH: SK2022459637

In Kosice, December 19th, 2025

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Tomas Janura – Managing Director