EU Declaration of Conformity

Manufacturer:

Plum Safety ApS
Mandelalléen 1,
5610 Assens
Denmark

SRN (Single Registration Number): DK-MF-000008672

Name of the product: Plum QuickFix plasters

Reference number:

Art No	Art Name
5511	Plum QuickFix Water resistant
5512	Plum QuickFix Elastic
5508	Plum QuickFix Elastic Long
5504	Plum QuickFix Elastic Mini
5518	Plum QuickFix Elastic Micro
5513	Plum QuickFix Detectable
5509	Plum QuickFix Detectable long
5515	Plum QuickFix Alu
5519	Plum QuickFix Alu Micro

Intended purpose: Plum QuickFix plasters are used as a first aid product as mechanical barrier and for absorption of exudates.

Basic UDI-DI: 5715205QFPLASTER01SS

Device classification: Class I, according to Annex VIII, Rule 4

This declaration of conformity is issued under the sole responsibility of Plum Safety ApS. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by Presafe Denmark A/S, Certificate No.: DGM-940.

All supporting documentation is retained at the premises of the manufacturer.

The medical devices comply with the state-of-the-art requirements referred to in the standards mentioned in the current edition of the Technical Documentation.

Reference to common specifications: Not Applicable

Signature for Plum Safety ApS:

Place and date:
Assens, 2023-03-28

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Katarzyna Luiza Grzych
Person Responsible for Regulatory Compliance