

EU Declaration of conformity

(EU) 2017/745 MDR

BERNER LTD
Hitsaajankatu 24
00810 Helsinki
Finland

EUDAMED SRN
EN-MF-000007402

Basic UDI-DI
6414505PBS3

Risk class
Class I

Product	PN	UDI-DI
FINGERBUTTON	FB30	6414505180763
FINGERDUAL	FD30	6414505180770
FIVE ACTION SWITCH	SW5R	6414505180756
PIKOBUTTON 30 BLACK	PB30-BLACK	6414505179521
PIKOBUTTON 30 BLUE	PB30-BLUE	6414505179545
PIKOBUTTON 30 GOLD	PB30-GOLD	6414505179569
PIKOBUTTON 30 GREEN	PB30-GREEN	6414505179491
PIKOBUTTON 30 ORANGE	PB30-ORANGE	6414505179538
PIKOBUTTON 30 SILVER	PB30-SILVER	6414505179552
PIKOBUTTON 30 WHITE	PB30-WHITE	6414505179514
PIKOBUTTON 30 YELLOW	PB30-YELLOW	6414505179507
PIKOBUTTON 30 250G BLACK	PB30J-BLACK	6414505179729
PIKOBUTTON 30 250G BLUE	PB30J-BLUE	6414505179699
PIKOBUTTON 30 250G GOLD	PB30J-GOLD	6414505179750
PIKOBUTTON 30 250G GREEN	PB30J-GREEN	6414505179675
PIKOBUTTON 30 250G ORANGE	PB30J-ORANGE	6414505179736
PIKOBUTTON 30 250G RED	PB30J-RED	6414505179668
PIKOBUTTON 30 250G SILVER	PB30J-SILVER	6414505179743
PIKOBUTTON 30 250G WHITE	PB30J-WHITE	6414505179712
PIKOBUTTON 30 250G YELLOW	PB30J-YELLOW	6414505179705
PIKOBUTTON 30 75G BLACK	PB30H-BLACK	6414505179620
PIKOBUTTON 30 75G BLUE	PB30H-BLUE	6414505179590
PIKOBUTTON 30 75G GREEN	PB30H-GREEN	6414505179583
PIKOBUTTON 30 75G ORANGE	PB30H-ORANGE	6414505179637
PIKOBUTTON 30 75G SILVER	PB30H-SILVER	6414505179644
PIKOBUTTON 30 75G WHITE	PB30H-WHITE	6414505179613



PIKOBUTTON 30 75G YELLOW	PB30H-YELLOW	6414505179606
PIKOBUTTON 30 75G GOLD	PB30H-GOLD	6414505179651
PIKOBUTTON 30 75G RED	PB30H-RED	6414505179576
PIKOBUTTON 30 RED	PB30-RED	6414505179484
PIKOBUTTON 30 WAT RESIS BLACK	PB30WR-BLACK	6414505179873
PIKOBUTTON 30 WAT RESIS BLUE	PB30WR-BLUE	6414505179866
PIKOBUTTON 30 WAT RESIS GREEN	PB30WR-GREEN	6414505179880
PIKOBUTTON 30 WAT RESIS RED	PB30WR-RED	6414505179859
PIKOBUTTON 50 250G BLACK	PB50J-BLACK	6414505180398
PIKOBUTTON 50 250G BLUE	PB50J-BLUE	6414505180367
PIKOBUTTON 50 250G GOLD	PB50J-GOLD	6414505180428
PIKOBUTTON 50 250G GREEN	PB50J-GREEN	6414505180350
PIKOBUTTON 50 250G ORANGE	PB50J-ORANGE	6414505180404
PIKOBUTTON 50 250G RED	PB50J-RED	6414505180343
PIKOBUTTON 50 250G SILVER	PB50J-SILVER	6414505180411
PIKOBUTTON 50 250G WHITE	PB50J-WHITE	6414505180381
PIKOBUTTON 50 250G YELLOW	PB50J-YELLOW	6414505180374
PIKOBUTTON 50 75G BLACK	PB50H-BLACK	6414505180305
PIKOBUTTON 50 75G BLUE	PB50H-BLUE	6414505180275
PIKOBUTTON 50 75G GOLD	PB50H-GOLD	6414505180336
PIKOBUTTON 50 75G GREEN	PB50H-GREEN	6414505180268
PIKOBUTTON 50 75G ORANGE	PB50H-ORANGE	6414505180312
PIKOBUTTON 50 75G RED	PB50H-RED	6414505180251
PIKOBUTTON 50 75G SILVER	PB50H-SILVER	6414505180329
PIKOBUTTON 50 75G WHITE	PB50H-WHITE	6414505180299
PIKOBUTTON 50 75G YELLOW	PB50H-YELLOW	6414505180282
PIKOBUTTON 50 BLACK	PB50-BLACK	6414505180213
PIKOBUTTON 50 BLUE	PB50-BLUE	6414505180183
PIKOBUTTON 50 GOLD	PB50-GOLD	6414505180244
PIKOBUTTON 50 GREEN	PB50-GREEN	6414505180176
PIKOBUTTON 50 ORANGE	PB50-ORANGE	6414505180220
PIKOBUTTON 50 RED	PB50-RED	6414505180169
PIKOBUTTON 50 SILVER	PB50-SILVER	6414505180237
PIKOBUTTON 50 WAT RESIS BLACK	PB50WR-BLACK	6414505180466
PIKOBUTTON 50 WAT RESIS BLUE	PB50WR-BLUE	6414505180459
PIKOBUTTON 50 WAT RESIS GREEN	PB50WR-GREEN	6414505180473
PIKOBUTTON 50 WAT RESIS RED	PB50WR-RED	6414505180435
PIKOBUTTON 50 WHITE	PB50-WHITE	6414505180206
PIKOBUTTON 50 YELLOW	PB50-YELLOW	6414505180190
PIKODUAL 30	PD30	6414505201055
PIKODUAL 30 250G	PD30J	6414505201079
PIKODUAL 30 75G	PD30H	6414505201062
PIKODUAL 50	PD50	6414505180480



PIKODUAL 50 250G

PD50J

6414505180664

PIKODUAL 50 75G

PD50H

6414505180572

Use

Control of various devices and communication excluding life supporting use and mobility control.

Under the sole responsibility of the manufacturer, we issue the EU declaration of conformity and declare that the product complies with the MDR requirements of Regulation (EU) 2017/745 on medical devices and complies with the following standards:

EN ISO 13485:2016 Medical devices - Quality management systems

EN ISO 14971:2019 Medical devices - Application of risk management

EN ISO 15223-1:2021 Medical devices – Symbols

EN ISO 10993-1:2020 Biological evaluation of medical devices – Evaluation and testing

The quality system has been assessed and approved in Annex V(3) to Directive 93/42/EEC certificate, certificate No is C-01-1127-672-19.

HELSINKI

Place

16.12.2024

Time

Annastiina Palmroth-Holst
Chief Business Officer, MedLab
Berner Ltd