

## Procedure Pack Statement

**Procedure Pack Producer:** Safeguard Medical Technologies Ltd.

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**EU Authorised Representative and Importer:**

Safeguard Technologies Ltd  
Willow Grove,  
Delgany, A63 XY89  
Co Wicklow,  
Ireland

**SRN:** IE-AR-000008867

**declares that the procedure pack:**

<b>Procedure Pack Name:</b>	BURNFREE BURNS KIT - MEDIUM
<b>Procedure Pack Code:</b>	MBKI-10
<b>Basic UDI-DI</b>	506048357BBKEJ
<b>UDI-DI</b>	05060483571430

- a) The mutual compatibility of the devices and other products has been verified in accordance with the manufacturer's instructions
- b) The Procedure Pack Producer of the procedure pack has evidence that the conformity assessment procedures have been applied to each medical device in the package.
- c) The procedure pack has been packaged and supplied with relevant information to users incorporating the information supplied by the manufacturers of the devices or other products that have been put together. Neither the original packaging nor the instructions for use for each product are changed.
- d) Each medical device in the procedure pack is intended to be used for its original intended purpose.

- e) The processes of assembling of the procedure pack have been subjected to documented methods of internal monitoring, verification, and validation, that are part of the Safeguard Medical Technologies ISO 13485 certified Quality Management System.

The appropriate registration has been made to MHRA, EUDAMED, as well as HPRA as the competent authority in Ireland, and the base for the SMT Authorised Representative in the EU.

Safeguard Medical Technologies Ltd. agrees to develop, implement and maintain the post-production experience monitoring process, including the notification of reportable events under the European Medical Vigilance System Guidelines.

This statement is based on the **Article 22 of MDR 2017/745**.

#### Procedure Pack Content:

Code	Description	Quantity
0515-250	Burnfree Dressing 5x15	2 pcs
1010-150	Burnfree Dressing 10x10	2 pcs
120B-24	Burnfree Gel 120 ml Bottle	1 pc
SD20-30	Burnfree 3.5g packets (20 pack box)	1 pc
3053	Conforming Bandage (FA0412)	2 pcs

This statement is issued under the sole responsibility of Safeguard Medical Technologies Ltd as the Procedure Pack Producer.

*Eva Havelkova*  
 Signed \_\_\_\_\_

Date: 05/05/2022 \_\_\_\_\_

QA/RA Director, Safeguard Medical Technologies Ltd

Revision Number	1
Issue Date	05/05/2022
Change Number	316_22

#### Version History

DC Number	Revision	Date	Description of Change
49_22	0	20/01/2022	First issue of document
316_22	1	05/05/2022	Update of component code for conforming bandage.

# DTF 202\_Procedure Pack Statement\_MBKI-10\_Rev 1

Final Audit Report

2022-05-05

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