EC Design Examination Certificate

Certificate No.:	Project No.:	Valid Until:
216145-2017-CE-IND-NA-PS	**PRJC-558191-2017-MSL-IND**	**14 November 2022**

This is to certify that:

Spinal Needle

Manufactured by:

Global Medikit Limited

Khasra No. 323 (MI), Camp Road
Selaqui 248 197, Dehradun
Uttarakhand, India

Has been assessed with respect to:

Examination of the design of the product as described in Annex II section 4 (Module B1) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Place and Date:
Høvik, 23 November 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Cathrine Wisbech

Cathrine Wisbech

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	2017-11-14

Products covered by this Certificate:

Type of medical device and identification no.:	**Medical Device Class:**	**GMDN code:**
Spinal Needle	III	NA
Short description of the Medical Device: Spinal needle is used in giving regional anaesthesia. Spinal anaesthesia is useful for surgery involving the lower extremities, perineum & lower abdomen. Medicine is injected through the needle into the spinal cord by piercing the dura membrane to induce anaesthetic block. It is made using stainless steel grade AISI 304. It is available in two variants - Quincke Bevel & Pencil Point in the sizes 18G,19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G. The device is packed in blister and is EO sterilized.		

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall inform Presafe of any intended change of the products detailed above and Presafe will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

Conformity declaration and marking of product

This Certificate must be accompanied with a valid EC Certificate Full Quality Assurance System.

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate