

EC Certificate Production Quality Assurance System

Certificate No.:
242609-2017-CE-AUS-NA-PS Rev. 1.0

Project No.:
PRJC-541126-2016-MSL-AUS

Valid Until:
05 December 2021

This is to certify that the quality system of:

Benra Pty Ltd Trading As Gelflex Laboratories

52 Mulgul Rd, Malaga, Perth WA 6090 Australia

For production and final product inspection/testing of:

Moulded Soft Contact Lenses

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.2.b and Annex V (Module D1) 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.

Place and Date:
Høvik, 07 May 2018

For:
DNV GL NEMKO PRESAFE AS



Tone Kolpus

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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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.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces certificate No. 204205-2016-CE-AUS-NA Rev.1.0 (NB 0434) following transfer of Notified Body functions to DNV GL Nemko Presafe AS (NB 2460), Changed Organization address	2017-09-18
1.0	Extension in scope - new products (in bold) added	2018-05-07

Products covered by this Certificate:

Product Description	Product Name	Class
Daily lenses	<ul style="list-style-type: none"> • Tinted (water 57%, Methafilcon B 43%) • Decorative (water 57%, Methafilcon B 43%) • Tinted (water 43%, Polyhema 57%) • Decorative (water 43%, Polyhema 57%) • Tinted (water 48% Formofilcon B 52%) 	Class IIa
2 Weekly lenses	<ul style="list-style-type: none"> • Tinted (water 55%, Methafilcon A 45%) • Decorative (water 55%, Methafilcon A 45%) • Tinted (water 43%, Polyhema 57%) • Decorative (water 43%, Polyhema 57%) • Tinted (water 48% Formofilcon B 52%) 	Class IIa
Monthly lenses	<ul style="list-style-type: none"> • Tinted (water 55%, Methafilcon A 45%) • Decorative (water 55%, Methafilcon A 45%) • Tinted (water 43%, Polyhema 57%) • Decorative (water 43%, Polyhema 57%) • Tinted (water 48% Formofilcon B 52%) 	Class IIa

The complete list of devices is filed with the Notified Body

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Sites covered by this certificate

Head Quarters & 1st Factory: Benra Pty. Ltd. Trading as Gelflex Laboratories(52 Mulgul Road, Malaga, Perth WA 6090 Australia)

2nd Factory: PT Gelflex Indonesia (Complex Sarana Ind. Point Blok A, Jln Engku Putri, No 11 Batam Ctr, Batam, Indonesia)

EU Representative

ISEMED srl, Via A. Altobelli Bonettin. 3/A 40026 Imola (BO) - Italy

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 fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

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