APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:
10000378173 -PA -NA -SGP

Valid Until:
27 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:

Benra Pty Ltd Trading As Gelflex Laboratories

originally issued in compliance with :

the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

A new EU representative, replacing the one stated on the certificate, has been accepted.

EU Representative
GELFLEX EUROPE B.V. Het Assink 8A 7496 CC Hengevelde, The Netherlands

Appendix History -		
Revision	**Description**	**Issued Date**
0.0	Original Appendix - new EU representative	26 November 2021

Place and date:
Høvik, 26 November 2021

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 3, 1363 Høvik, Norway

Hazem Tinawi
Technical Reviewer

EC CERTIFICATE
Production Quality Assurance

Certificate no.:
10000378173-PA-NA-SGP

Initial certification date:
24 May 2021

Valid Until:
27 May 2024

This is to certify that the management system of
Benra Pty Ltd trading as Gelflex Laboratories
52 Mulgul Road, Malaga, Perth WA 6090, Australia

For design, production and final product inspection/testing of:
Moulded Soft Contact Lenses

has been assessed and found to comply with respect to:
the conformity assessment procedure described in Annex V of Council Directive 93/42/EEC on Medical Devices, as amended

Place and date:
Høvik, 24 May 2021

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 3, 1363 Høvik, Norway

Mariann Jeremiassen
Principal Assessor

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

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**	**Issued Date**
0.0	Original Certificate	**2021-05-24**

Products covered by this Certificate:		
Product Description	**Product Name**	**Class**
Daily Contact Lenses Tinted (water 57%, Methafilcon B 43%)	Sofclear	IIa
	FreeVision	
	White box	
	TopVue	
	Chiara	
	Auga	
	e-CLASSIC	
	Elegance	
	Dimple	
Daily Contact Lenses Decorative (water 57%, Methafilcon B 43%)	Ningaloo	IIa
	FreeVision	
	White box	
	Sofclear Colours	
Daily Contact Lenses Tinted (water 43%, Polyhema 57%)	Sea Clear	IIa
	Hydrolens	
Daily Contact Lenses Decorative (water 43%, Polyhema 57%)	Sofclear Colours	IIa
	Aquacolor	
	Crazy	

	FreeVision	
2 Weekly Contact Lenses Tinted (water 55%, Methafilcon A 45%)	Sofclear	IIa
	FreeVision	
	White box	
	Chiara	
2 Weekly Contact Lenses Decorative (water 55%, Methafilcon A 45%)	Ningaloo	IIa
	FreeVision	
	Sofclear Colours	
	Sofclear Enhance	
Monthly Contact Lenses Tinted (water 55%, Methafilcon A 45%)	Sofclear	IIa
	FreeVision	
	White box	
	TopVue	
	Mediclear	
	Chiara	
Monthly Contact Lenses Decorative (water 55%, Methafilcon A 45%)	Ningaloo	IIa
	FreeVision	
	Sofclear Colours	
	Dimple	
	Medicolor	
	Sofclear Enhance	
Monthly Contact Lenses Tinted (water 43%, Polyhema 57%)	Sea Clear	IIa
	Hydrolens	
	Polylite	
	Belcon	
	Natural Clear	

Monthly Contact Lenses Decorative (water 43%, Polyhema 57%)	Sofclear Colours	IIa
	Crazy	
	FreeVision	
	Polylite	
	Crystal Color	
	Elegance	
	Seasons	
	Natural Look	
	Colors	
	Aquacolor	
	Leila&Leila	

Sites covered by this certificate	
Site Name	**Site Address**
Head Quarters & First Factory - "Gelflex Laboratories"	52 Mulgul Road, Malaga, Perth WA 6090 Australia
Second Factory – “PT Gelflex Indonesia”.	Complex Sarana Ind. Point Blok A, Jln Engku Putri, No 11 Batam Ctr, Batam, Indonesia

EU Representative
ISEMED srl - Via P. Togliatti 19/X - 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 the Notified Body of any intended updating of the quality system and the Notified Body 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. Notified Body 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.