



DECLARATION OF CONFORMITY

Manufacturer:

OPRO International Limited
24 Mark Road
Hemel Hempstead
HP2 7BN
United Kingdom

EUDAMED SRN:

GB-MF-000004793

Authorized Representative:

Eurolink Europe Compliance Limited
25 Herbert Place
Dublin D02 AY86
Republic of Ireland

EUDAMED SRN:

GIE-AR-000002852

We the undersigned certify and declare under our sole responsibility that the following apparatus

Conforming Apparatus:

Mouthguard Reusable

Basic UDI-DI:

506014357 Nightguard B8

***Device Name, Model Name and UDI-DI
Number:***

See Page 2

Risk Class:

Class I – MDR Annex VIII Rule 1

Technical Document Reference No:

TECHNICAL FILE 03 R 01

Common Specifications

EN ISO 14971:2019 Medical Devices – Application of Risk
Management to Medical Devices
Medical Devices Regulations – Annex I, General Requirements

conforms to the requirements of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF
THE COUNCIL OF 5 April 2017 on medical devices

Signed:

A handwritten signature in blue ink, appearing to read "Anthony Lovat", written over a light blue horizontal line.

Dr Anthony Lovat
Managing Director
OPRO International Limited

Date: 18 July 2025

Issued: Dublin, Republic

Device Name	Model Name	UDI-DI
Nightguard	One Size	5060143577659