

MEDICOM HEALTHCARE LIMITED

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### **DECLARATION OF CONFORMITY**

We **Medicom Healthcare**, 235 Hunts Pond Road, Fareham, Hampshire, PO14 4PJ U.K., hereby declare that the device **Carbomer 0.2% Eye Gel 10g (Perborate Preservative)** is a sterile ophthalmic eye gel and it is in conformity with the provisions of the **93/42/EEC on the Medical Device Directive** when used in accordance with the instructions contained in the product documentation.

The medical device **Carbomer 0.2% Eye Gel 10g (Perborate Preservative)** is classified as **Class IIa** since it satisfies the ruling of Annex IX: Classification Criteria III, Classification 2 Invasive Device; 2.1. Rule 5 of the Medical Device Directive 93/42/EEC as amended by 2007/47/EC.

A Quality Management System based on the ISO 13485 (Current Version) (Certificate GB13/87782) has been implemented towards production and quality assurance.

We further declare that SGS (CE 0120) have been appointed as our notified body to undertake the provision of Annex V of the 93/42/EEC Medical Device Directive (Certificate GB13/87782) for **Carbomer 0.2% Eye Gel 10g (Perborate Preservative)**.

**Intended use:** It is intended for dry eye sensations and provides soothing relief for sore eyes from grit, itchiness and other foreign body irritations.

Signature:



Date:



**Christian Martin**  
**Managing Director**  
**Medicom Healthcare Limited**

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EMAIL: [info@medicomhealthcare.com](mailto:info@medicomhealthcare.com)WEBSITE: [www.medicomhealthcare.com](http://www.medicomhealthcare.com)**List of Products Conformed within Declaration of Conformity**

Unique Product Code (UPOC)	Order	Product Name	Description
01701514M9		Xailin Gel (EN, IT, FR, RO)	Carbomer 0.2% Eye Gel Perborate 10g (CE)
01701514M6		Xailin Gel (EN, IT, FR, TR)	Carbomer 0.2% Eye Gel Perborate 10g (CE)
01701514M7		Xailin Gel (FR, DE, NL, PL)	Carbomer 0.2% Eye Gel Perborate 10g (CE)
01701514ME		Xailin Gel (FR, DE, NL, RO)	Carbomer 0.2% Eye Gel Perborate 10g (CE)
01701514M4		Xailin Gel (FR,EN,DE,IT)	Carbomer 0.2% Eye Gel Perborate 10g (CE)
01701814M4		Xailin Gel (Sample) (FR,EN,DE,IT)	Carbomer 0.2% Eye Gel Perborate 10g (CE)
01701516ES		Xilin Gel (ES)	Carbomer 0.2% Eye Gel Perborate 10g (CE)
01701816ES		Xilin Gel (Sample) (ES)	Carbomer 0.2% eye Gel Perborate 10g (CE)