

MEDICOM HEALTHCARE LIMITED

FORUM 3, SOLENT BUSINESS PARK,
WHITELEY, FAREHAM,
HAMPSHIRE, PO15 7FH, UK

TELEPHONE: +44 (0)1489 574119

FAX: +44 (0)1489 564009

EMAIL: info@medicomhealthcare.com

WEBSITE: www.medicomhealthcare.com

DECLARATION OF CONFORMITY

We, **Medicom Healthcare Limited**, 235 Hunts Pond Road, Titchfield Common, Fareham, PO14 4PJ, U.K., hereby declare that the device **Carbomer Gel 0.2% w/w** with Cetrimide preservative is a sterile ophthalmic 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 Gel 0.2% w/w** 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 13485:2003 has been implemented towards production and quality assurance.

We further declare that SGS 0120 have been appointed as our notified body to undertake the provision of Annex V of the 93/42/EEC Medical Device Directive for **Carbomer Gel 0.2% w/w**.

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

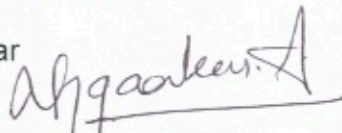
Signature:

Date: 15-09-2013

Simon Martin
Director



Atul Ajgaonkar
Director



Medicom Healthcare Ltd