

MEDICOM HEALTHCARE LIMITED

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DECLARATION OF CONFORMITY

We, **Medicom Healthcare Limited**, 235 Hunts Pond Road, Fareham, Hampshire, PO14 4PJ, U.K., hereby declare that the device **Lubricating Eye Ointment** is a preservative free sterile ophthalmic ointment 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 **Lubricating Eye Ointment** is classified as **Class IIa** since, it satisfy 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 (Certificate GB13/87782) has been implemented towards production quality assurance system.

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 GB 13/87784) for **Lubricating Eye Ointment**.

Intended use: It is intended for dry eye sensations as well as for a moisture loss barrier for patients undergoing non-ophthalmic surgery.

Signature:



Christian Martin
Managing Director
Medicom Healthcare Limited

Date:

22/08/17

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List of Products Conformed within Declaration of Conformity

Unique Product Order Code (UPOC)	Product Description	Product Name
01712310M9	Lubricating Eye Ointment PF 5.0g (CE)	Xailin Night 5.0g (EN, IT, FR, RO)
01712310M6	Lubricating Eye Ointment PF 5.0g (CE)	Xailin Night 5.0g (EN, IT, FR, TR)
01712310M7	Lubricating Eye Ointment PF 5.0g (CE)	Xailin Night 5.0g (FR, DE, NL, PL)
01712310ME	Lubricating Eye Ointment PF 5.0g (CE)	Xailin Night 5.0g (FR, DE, NL, RO)
01712310M4	Lubricating Eye Ointment PF 5.0g (CE)	Xailin Night 5.0g (FR,EN,DE,IT)
01713210M4	Lubricating Eye Ointment PF 3.5g (CE)	Xailin Night 3.5g (Sample) (FR,EN,DE,IT)
01712315ES	Lubricating Eye Ointment PF 5.0g (CE)	Xilin Night 5.0g (ES)
01713215ES	Lubricating Eye Ointment PF 3.5g (CE)	Xilin Night 3.5g (Sample) (ES)