

FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/024-2016

according to Annex II of Directive 93/42/EEC on Medical Devices as amended

MTIC Intercert hereby declares that an examination of the under mentioned Full Quality Assurance System has been carried out following the requirements of the legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on Medical Devices.

MTIC Intercert certifies that the Full Quality Assurance System conforms with the relevant provisions of the aforementioned legislation. The validity of this certificate is subjected to the positive result of required surveillance audits.

MANUFACTURER:

ENTOD PHARMACEUTICALS LIMITED

Ashirwad Building, Opp. Badi Masjid S.V. Road Bandra (W),

Mumbai - 400050 INDIA

DEVICE/S:

Ocular lubricating and comfort solution

MODEL/S:

- Carmellose Sodium 0.5% Eye Drops LOC Tears Eye Drops
- Carmellose Sodium 1.0% Eye Drops I-Dew DS Aquagel
- Sodium Hyaluronate 0.18% Eye Drops I-Dew Ultra Eye Drops
- Hypromellose 0.7% Ophtalmic Solution I-Dew Soothe Eye Drops

FIRST ISSUE:

23/05/2016

CURRENT ISSUE: 12/12/2019

REVISION Nr.: 01

This certificate does not cover the period from the 24.05.2019 to 11.12.2019

Dipl - Ing. Feridoon Sergizzarea

MTIC INTERCERT Certification Body

F-PC-DM-14-01-01 Rev.0.1 en

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