

EC DECLARATION OF CONFORMITY

According to Annex II (exemption of section 4) of Council Directive 93/42/EEC concerning Medical Devices

Reference No

: 305020-08

Manufacturer

SIDAPHARM P.C.

Facility Address

21, Stageiriti & 24, Em. Fili str., GR-54352, Thessaloniki, Greece

Product

S_{IDA}-SPEARS PVA Eye Spears

Ref. No: 70001

Olie Medical PVA Eye Spears

Ref. No: 70001 GMDN: 13704

Classification

Is, according to Annex IX of Council Directive 93/42/EEC

Guidelines Applicable:

MEDDEV 2.4/1 Rev. 9 - June 2010 Rule 1

This Declaration of Conformity is issued under the sole responsibility of the manufacturer. SIDAPHARM hereby declares that the aforementioned products comply with all the essential requirements of Council Directive 93/42/EEC, concerning Medical Device, as amended by 2007/47/EC.

The compliance of this applicable quality assurance system has been certified by the "National Evaluation Center of Quality & Technology in Health S.A", which is a Notified Body, according to Council Directive 93/42/EEC, with identification number 0653.

The present is issued, according to EC Certificate No.: 3050201023M, whose original expiry date was June 3, 2023, but it has been granted an extension, according to Regulation (EU) 2023/607, till May 26, 2024.

The present replaces any previous declaration has been issued for these products.

For and on behalf of: SIDAPHARM P.C.

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Diana Mochintra General Manager

Date: 30/06/2023