SIDAPHARM
Ophthalmic & Medical Disposable Products

# MANUFACTURER'S DECLARATION

## in regards to Regulation 2023/607

with respect to the certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD), (Directive Certificates) and their validity per Article 120.2 of Regulation (EU) 2017/745 on Medical Devices (MDR) as amended by Regulation (EU) 2023/607 of 20 March 2023 and with respect to the devices' and their manufacturer's compliance with the conditions to continued placing on the market or putting into service per Article 120.3c of the MDR:

| | |
|---|---|
| Manufacturer name | **SIDAPHARM P.C.** |
| Manufacturer address | 21, Stageiriti & 24, Em.Fili str.<br>Thessaloniki GR-54352, Greece |
| Single Registration Number (SRN) | GR-MF-000016490 |

| | |
|---|---|
| Notified body name | HTCert |
| Notified body number | 2803 |
| **Directive certificate number to which this confirmation is made** | **1828C04210505** |
| Date of validity as indicated on the Directive certificate | 03/06/2023 |
| **End date of extended validity/ transition period** | **26/05/2024** |

We, as the manufacturer, declare under our sole responsibility:

- ✓ for the above listed **Directive certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- ✓ the listed **devices** in the attached schedule and we, as their manufacturer, are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- ✓ The above listed Directive certificate covering the devices mentioned in the Schedule was issued after 25 May 2017, was valid on 26 May 2021, was not withdrawn by 20 March 2023, and did not expire before 20 March 2023.
  - As this Certificate was set to expire after 20 March 2023, a formal application to the notified body in accordance with Section 4.3, first subparagraph, of Annex VII MDR for conformity assessment will be made/submitted to a notified body no later than 26 May 2024 for the devices listed in the attached schedule and a signed written agreement will be in place in accordance with Section 4.3, second subparagraph, of Annex VII MDR before 26 September 2024.

Digitally signed by Pereteatco Alina
Date: 2023.09.26 12:50:12 EEST
Reason: MoldSign Signature
Location: Moldova

- As this Certificate was set to expire after 20 March 2023 and before 26 May 2024, if SIDAPHARM, as the manufacturer, does not lodge an application for conformity assessment by 26 May 2024, the transition period will end on 26 May 2024.

✓ A Quality Management System (QMS) in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024

✓ The Devices as listed in the attached schedule
- continue to comply with the MDD,
- have not been significantly changed in their design and intended purpose since 26 May 2021,
- do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

✓ We acknowledge that requirements relating to **post-market surveillance, vigilance, registration of economic operators** and of devices in accordance with MDR apply for the device families as listed in the attached schedule.

Signed for and on behalf of the manufacturer:

SIDAPHARM P.C.
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Thessaloniki GR-54352, Greece
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VAT Reg. No.: EL997296038
Registration Number: 144520204000

Diana Mochintra

General Manager
SIDAPHARM P.C.

Thessaloniki, 26/05/2023

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# SCHEDULE OF DEVICES

| Identification of the device | | | Validity date as indicated on the Directive certificate | Extended validity date or transition period |
|---|---|---|---|---|
| **Medical Device** | **Brand Name** | **Model/ Ref.No.** | | |
| Ophthalmic Microsurgical Knives | **SIDAPHARM; Olie Medical** | 62000; 62001; 62002; 62003; 62003-1; 62004; 62005; 62007; 62009; 62010; 62012; 62016; 62016-DB; 62017; 62017-DB; 62018; 620181-DB; 62018-DB; 62018-1; 62019; 62019-DB; 62020; 62020-DB; 62021; 62027; 62052; 62052-DB; 62055; 62056; 62056-DB; 62057; 62057-DB; 62058; 62058-DB; 62059; 62059-DB;<br><br>62000-SF; 62001-SF; 62002-SF; 62003-SF; 62003-1SF; 62004-SF; 62005-SF; 62007-SF; 62009-SF; 62010-SF; 62012-SF; 62016-SF; 62016-DBSF; 62017-SF; 62017-DBSF; 62018-SF; 62018-DBSF; 62018-1SF; 620181-DBSF; 62019-SF; 62019-DBSF; 62020-SF; 62020-DBSF; 62021-SF; 62052-SF; 62052-DBSF; 62056-SF; 62056-DBSF; 62057-SF; 62057-DBSF; 62058-SF; 62058-DBSF; 62059-SF; 62059-DBSF; 62060-SF; 62060-DBSF;<br><br>62000-NS; 62000-SFNS; 62001-NS; 62001-SFNS; 62002-NS; 62002-SFNS; 62003-NS; 62003-SFNS; 62003-1NS; 62003-1SFNS; 62004-NS; 62004-SFNS; 62005-NS; 62005-SFNS; 62007-NS; 62007-SFNS; 62009-NS; 62009-SFNS; 62010-NS; 62010-SFNS; 62012-NS; 62012-SFNS; 62016-NS; 62016-SFNS; 62016-DBNS; 62016-DBSFNS; 62017-NS; 62017-SFNS; 62017-DBNS; 62017-DBSFNS; 62018-NS; 62018-SFNS; 62018-DBNS; 62018-DBSFNS; 62018-1NS; 62018-1SFNS; 620181-DBNS; 620181-DBSFNS; 62019-NS; 62019-SFNS; 62019-DBNS; 62019-DBSFNS; 62020-NS; 62020-SFNS; 62020-DBNS; 62020-DBSFNS; 62021-NS; 62021-SFNS; 62052-NS; 62052-SFNS; 62052-DBNS; 62052-DBSFNS; 62056-NS; 62056-SFNS; 62056-DBNS; 62057-NS; 62057-SFNS; 62057-DBNS; 62057-DBSFNS; 62058-NS; 62058-SFNS; 62058-DBNS; 62058-DBSFNS; 62059-NS; 62059-SFNS; 62059-DBNS; 62059-DBSFNS; 62060-NS; 62060-SFNS; 62060-DBNS | 03/06/2023 | **26/05/2024** |

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| Identification of the device | | | Validity date as indicated on the Directive certificate | Extended validity date or transition period |
|---|---|---|---|---|
| **Medical Device** | **Brand Name** | **Model/ Ref.No.** | | |
| Ophthalmic Microsurgical Cannulas | **SIDAPHARM; Olie Medical** | 77006; 77007; 77008; 77081; 77104; 77082; 77044; 77001; 77003-1; 77056; 77003; 77046; 77004; 77015; 77016; 77062; 77010; 77012; 77013; 77014; 77063; 77067; 77068; 77073; 77074; 77070; 77072; 77027; 77028; 77032; 77030; 77038; 77022; 77025; 77021; 77083; 77084; 77006; 77007; 77082; 77004; 77010; 77013; 77014; 77032; 77025; 77021 | 03/06/2023 | **26/05/2024** |
| Trypan Blue Ophthalmic Solution | **$S_{IDA}$-BLUE** | 84000 | | |
| | **$S_{IDA}$-BLUE PFS** | 84001 | | |
| Balanced Salt Solution (BSS) | **SIDAPHARM** | 76001 | | |
| HPMC Ophthalmic Solution | **$S_{IDA}$-HPMC 2%** | 10003 | | |