SIDAPHARM®
Ophthalmic & Medical Disposable Products

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to:

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer Name:	**SIDAPHARM P.C.**
Manufacturer address and contact details:	21, Stageiriti & 24, Em.Fili str. Thessaloniki GR-54352, Greece Tel.: +30 2310906660 E-mail: info@sidapharm.gr
Single Registration Number (SRN):	GR-MF-000016490

Notified body name:	HTCert
Notified body number:	2803
Directive certificate numbers to which this confirmation is made:	**1828C04210505** **1828C04210204**
Original expiry date as indicated on the Directive Certificates prior to the extension of the validity:	*See attached schedule*
End date of extended validity/ transition period:	*See attached schedule*

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

- ✓ for the above listed **Directive Certificates** (see also attached Schedule) 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 **Directive Certificates** covering the listed devices as listed above and in the attached Schedule were valid on 26 May 2021 and have not been withdrawn afterwards.
- ✓ Formal applications to the Notified Body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been submitted by us to a Notified Body before 26 May 2024 for the devices listed in the attached schedule or their substitutes and a signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

- ✓ A **Quality Management System (QMS)** in accordance with Article 10(9) MDR is in place.
- ✓ **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,
  - 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.

Signed for and on behalf of the manufacturer:

SIDAPHARM P.C.
Thessaloniki, 11/07/2024

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Diana Mochintra
General Manager

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SCHEDULE OF DEVICES

The above Manufacturer's Declaration is valid for the following devices:

Identification of the devices	Directive Certificate No. to which this confirmation is made	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/ contract signed	End date of extended validity / transition period
Ophthalmic Microsurgical Knives / Brand Name: **SIDAPHARM** Models: 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; 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; 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	1828C04210505	03/06/2023	HTCert 2803	HTCert 2803	31/12/2028

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Ophthalmic Microsurgical Cannulas Brand Name: **SIDAPHARM** Models: 77001; 77003; 77003-1; 77004; 77006; 77007; 77008; 77010; 77012; 77013; 77014; 77015; 77016; 77021; 77022; 77025; 77027; 77028; 77030; 77032; 77038; 77044; 77046; 77056; 77062; 77063; 77067; 77068; 77070; 77072; 77073; 77074; 77081; 77082; 77083; 77084; 77104 Brand Name: **Olie Medical** Models: 77004; 77006; 77007; 77010; 77013; 77014; 77021; 77025; 77032; 77082	1828C04210505	03/06/2023	HTCert 2803	HTCert 2803	31/12/2028
Trypan Blue Ophthalmic Solution Brand Name: **SIDA-BLUE** Model: 84000 Brand Name: **SIDA-BLUE PFS** Model: 84001	1828C04210505	03/06/2023	HTCert 2803	HTCert 2803	31/12/2028
Balanced Salt Solution (BSS) Brand Name: **SIDAPHARM** Models: 76000; 76001	1828C04210505	03/06/2023	HTCert 2803	HTCert 2803	31/12/2028
Sodium Hyaluronate Ophthalmic Solution Brand Name: **SIDA-VISC** Models: 10000; 10002; 10005; 10006; 10007; 10009; 10010; 10014; 10016; 10018; 10030 Brand Name: **SUPRALON** Variations: 1%; 3%	1828C04210204	26/05/2024	HTCert 2803	HTCert 2803	31/12/2028
Hypromellose Ophthalmic Solution Brand Name: **SIDA-HPMC 2%** Models: 10003; 10011	1828C04210204	26/05/2024	HTCert 2803	HTCert 2803	31/12/2028

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Disposable Cartridge and Injector Brand Name: **SIDA-JECT** Models: SPL2000; SPB2200	1828C04210204	26/05/2024	HTCert 2803	HTCert 2803	31/12/2028
PVA Eye Spears Brand name: **SIDA-SPEARS** Models: 70002; 70003; 70004; 70005; 70006; 70007; 70008; 70009 Brand name: **Olie Medical** Model: 70007	1828C04210204	26/05/2024	HTCert 2803	HTCert 2803	31/12/2028