LNE
Le progrès, une passion à partager

Certification
Médical-Santé
Notified Body N° 0459

ATTESTATION */ CERTIFICATE* **N° 9169 rev. 4**
Délivrée à Paris le 19 octobre 2017
Issued in Paris on October 19th, 2017

ATTESTATION CE */ EC CERTIFICATE*

Approbation du Système d'assurance Qualité de la Production/ *Approval of Production Quality Assurance System*
ANNEXE V point 3 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX V section 3 DIRECTIVE 93/42/EEC concerning medical devices
Pour les dispositifs de classe IIb ou III, un certificat CE de type est requis
For class IIb or III devices, a EC type certificate is required

Fabricant */ Manufacturer*

PHAKOS
62 rue Kléber
93100 MONTREUIL FRANCE

Catégorie du(des) dispositif(s) */ Device(s) category*
Cryode stérile à usage unique

Sterile single use Cryo Probe

Voir détails sur addendum
See attachment for additional information

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé P159672, le système d'assurance qualité - pour la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe V point 3 de la Directive 93/42/CEE.

LNE/G-MED certifies that, on the basis of the results contained in the file referenced P159672, the quality system - for manufacturing and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex V section 3.

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité */ Effective date :* **October 19th, 2017 (included)**
Valable jusqu'au */ Expiry date :* **November 20th, 2020 (included)**

Laboratoire national de métrologie et d'essais LNE

On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager

LNE - 9169 rev. 4
Renouvelle le certificat 9169-3

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Certification
Médical-Santé

Addendum au certificat n° 9169 rev. 4 **page 1/1**
Addendum of the certificate n° 9169 rev. 4
Dossier / *File* N° P159672

Identification des dispositifs / *Identification of devices*

Désignation du dispositif	Référence commerciale	Classe du DM
Cryode à Décollement stérile à usage unique	MV CY100	IIa

Identification des sites et activités / *Identification of locations and activities*

- **PHAKOS - 62, rue Kléber - 93100 MONTREUIL – France**

  Siège social – Activités de fabrication et contrôle final
  Headquarter – Activities of manufacturing and final control

LNE/G-MED	0459

Laboratoire national de métrologie et d'essais • LNE

On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager

Laboratoire national de métrologie et d'essais • Établissement public à caractère industriel et commercial
LNE/G-MED • Organisme notifié n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr

PHAKOS
phakos@phakos.com

DECLARATION CE DE CONFORMITE
EC DECLARATION OF CONFORMITY

Directive 93/42/CEE Incluant les modifications de la directive 2007/47/CE
Directive 93/42 / EEC Including the amendments to Directive 2007/47 / EC

Nous soussignés, *We the undersigned,*

PHAKOS
62, Rue Kléber
93100 Montreuil
France

, déclarons sous notre seule et entière responsabilité que le dispositif médical
declare under our sole and entire responsibility that the medical device

Cryode stérile à usage unique
Sterile single use Cryo Probe

Reference MV CY 100

Classification du dispositif
Classification of the device

II A

, est conforme aux exigences applicable de la directive 93/42/CEE modifiée par la directive 2007/47/CE.
,complies with the requirements of Directive 93/42 / EEC as amended by Directive 2007/47 / EC.

Cette déclaration est basé sur *This statement is based on*:

1. le dossier technique « MV CY 100 » établit conformément à l'annexe VII
   The technical file "MV CY 100" in accordance with Annex VII
2. L'attestation CE de conformité à l'annexe V point 3 de la directive 93/42/CEE **n° 9169 Révision 4,** délivré par le LNE/G-MED le 19/10/17.
   The EC certificate of conformity with point 3 of Annex V to Directive 93/42 / EEC n ° 9169 Revision 4, issued by LNE / G-MED on 19/10/17.

CE
0459

Organisme Notifié
LNE/G-MED
1, rue Gaston Boissier
75724 Paris Cedex 15

Début de validité/ *Effective date* **: 23 Octobre 2017 inclus/***inclued*
Valable jusqu'au/ *Expiry date* **: 20 Novembre 2020 inclus/***inclued*

Olivier Aumaître, Gérant

PHAKOS
62, rue Kléber
93100 Montreuil
Tél. : 01 49 88 74 00
Fax : 01 49 88 72 88

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Le progrès, une passion à partager

Certification Médical-Santé G MED

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 11949 rev. 5

Le LNE certifie que le système de management de la qualité développé par

LNE certifies that the quality management system developed by

PHAKOS
62 rue Kléber
93100 MONTREUIL FRANCE

pour les activités
for the activities

Conception, fabrication et distribution de dispositifs médicaux et chirurgicaux pour l'ophtalmologie

Design, manufacturing and distribution of medical and surgical devices for ophthalmology

réalisées sur le(s) site(s) de
performed on the location(s) of

PHAKOS
62 rue Kléber 93100 MONTREUIL FRA

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

NF EN ISO 13485 : 2012

Début de validité */ Effective date :* **October 19th, 2017 (included)**
Valable jusqu'au */ Expiry date :* **February 28th, 2019 (included)**
Etabli le */ Issued on :* **October 19th, 2017**

Laboratoire national de métrologie et d'essais LNE

On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0038
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED_SQ_SPE-V0-04-2016

LNE N° 11949–5
Ce certificat est délivré selon les règles de certification G-MED / This certificate is issued according to the rules of G-MED certification

Renouvelle le certificat 11949-4

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 3, 2017

PHAKOS
% J.D. Webb
Official Correspondent
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681

Re: K162756
Trade/Device Name: PHAKOS Disposable Retinal Cryo Probe
Regulation Number: 21 CFR 886.4170
Regulation Name: Cryophthalmic Unit
Regulatory Class: Class II
Product Code: HRN
Dated: April 12, 2017
Received: April 13, 2017

Dear J.D. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing
(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2017

CERTIFICATE OF REGISTRATION

This certifies that:

PHAKOS
62 Rue Kleber
93100 Montreuil Seine-Saint-Denis
FRANCE

Is registered with the U.S. Food and Drug Administration pursuant to Title 21, Parts 803 and 807 et seq. of the United States Code of Federal Regulations, such registration having been verified as currently effective on, and as the date hereof, by The OrthoMedix Group, Inc.

Establishment Registration: 3006142778
Operator Number: 10024840

This certificate does not denote endorsement or approval of the certificate holder's device or establishment by the U.S. Food and Drug Administration. The OrthoMedix Group, Inc. assumes no liability to any person or entity in connection with the foregoing. The OrthoMedix Group, Inc. is a private registration agent not affiliated with the U.S. Food and Drug Administration.

THE ORTHOMEDIX GROUP, INC.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

J.D. Webb
President
The OrthoMedix Group, Inc.
Dated January 2, 2017