N. di protocollo / *Protocol No.*: **FP-4529/24-nc10**

Data / *Date*: **2024/07/19**

Lettera di conferma dell'Organismo Notificato / *Notified Body Confirmation Letter*
Riferimento / *Reference*: 1002C05166770C_CL

A chi di competenza / *To whom it may concern,*

Conferma dello stato di una domanda formale, di un accordo scritto e di un'appropriata sorveglianza nell'ambito del Regolamento (UE) 2023/607 che modifica i Regolamenti (UE) 2017/745 e 2017/746 per quanto riguarda le disposizioni transitorie per alcuni dispositivi medici e dispositivi medico-diagnostici in vitro.

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

La presente lettera conferma che IMQ S.p.A., un Organismo Notificato (nel seguito, "ON") designato ai sensi del Regolamento (UE) 2017/745 (MDR) e identificato con il numero 0051 su NANDO, ha ricevuto una domanda formale in conformità alla sezione 4.3, primo comma dell'Allegato VII del MDR e firmato un accordo scritto in conformità alla sezione 4.3, secondo comma dell'Allegato VII del MDR con il seguente **fabbricante**:

*This letter confirms that IMQ S.p.A., a Notified Body (hereinafter, "NB") designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0051 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following **manufacturer***:

NOVAX PHARMA S.A.M.

20, Av. De Fontvieille LE CORONADO – 7° ETG – N°3 98000 MONACO, MC PRINCIPAUTE DE MONACO

SRN: MC-MF-000011256

EC CERTIFICATE

Certificate No 1934/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

NOVAX PHARMA SAM

98000 MONACO - 20,Av. De Fontvieille,Le Coronado,7° Etg, 3 (MCO) - Monaco

manages in the factory of:

98000 MONACO - 20,Av. De Fontvieille,Le Coronado,7° Etg, 3 (MCO) - Monaco

a quality assurance system ensuring the conformity of the following products:

Lubricant ophthalmic solutions with sodium hyaluronate

Sterile wipes for ophthalmic use

Ophthalmic solutions with sodium hyaluronate and sodium chloride 5%

Wetting and lubricating ophthalmic solutions

Lubricant ophthalmic solution with sodium hyaluronate spray

Eyelid foams

series and type refs in the Annex

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

DM16-0004410-01; DM17-0012269-01; DM17-0016717-01; DM17-0019462-01; DM18-0023521-01; DM18-0029039-01; DM18-0030362-01; DM19-0038813-01; DM19-0042511-01; DM19-0046044-01; DM19-0047010-01; DM20-0048282-01; DM20-0048500-01; DM20-0055276-01; DM20-0057459-01; DM21-0060709-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2017-03-13
Updated:	2021-03-11
Substitution Date:	2020-11-02
Expiry Date:	2024-05-26

IMQ DocuSign

EC CERTIFICATE

Certificate No 1869/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

NOVAX PHARMA SAM

98000 MONACO - 20,Av. De Fontvieille,Le Coronado,7° Etg, 3 (MCO) - Monaco

manages in the factory of:

98000 MONACO - 20,Av. De Fontvieille,Le Coronado,7° Etg, 3 (MCO) - Monaco

a quality assurance system ensuring the conformity of the following products:

Contact lens care solutions

Wetting and lubricating ophthalmic solutions

Type ref. as to document "CODE PRODUCTS LIST Ref TF 01" rev. 04 dated 07/04/2020"; valid only if provided with IMQ stamp.
Trade mark NOVAX PHARMA

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

DM15A0483599-01; DM17-0015589-01; DM18-0026876; DM19-0038813-01; DM19-0042511-01; DM19-0046044-01; DM19-0047010-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date: 2016-04-19
Updated: 2020-04-24
Substitution Date: 2019-11-18
Expiry Date: 2024-05-26

DocuSign

IMQ

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www.imq.it

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CERTIFICATO N.
CERTIFICATE N. 9124.NVXP

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

NOVAX PHARMA SAM

20 AVENUE DE FONTVIEILLE - MC 98000 MONACO

UNITA' OPERATIVE / *OPERATIVE UNITS*

20 AVENUE DE FONTVIEILLE - MC 98000 MONACO

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Gestione della progettazione e della fabbricazione ed immissione in commercio di dispositivi oftalmici non attivi

Management of the design and of manufacturing and placing on the market of non-active ophthalmic devices

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2016-04-07	2022-01-19	2025-04-07

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
SGQ N° 005 A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

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Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ
www.cisq.com
CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.