



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System No. 20 0434 QS/NB

The quality system of manufacturer

Pollux Nova a.s.

U Křížku 572, 252 43 Průhonice, Czech Republic

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):

Hydrophobic Intraocular Lens

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2021-05-21
Valid until: 2024-05-27
First Issued: 2020-09-30
Revision: a



Date: 2021-05-21

Mgr. Jiří Heš
Representative of the Notified Body No. 1023



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Annex to EC Certificate No. 20 0434 QS/NB

issued for manufacturer:

Pollux Nova a.s.
U Křížku 572, 252 43 Průhonice, Czech Republic

Product(s):

Name: **monofocal clear hydrophobic
intraocular lens**

Trade name(s): MONPHOBA CLEAR

Model(s): Optical power range from -5,0 to +40,0 D in 0,5 D steps

Class: IIb

GMDN: 35658

Name: **monofocal yellow tinted hydrophobic
intraocular lens**

Trade name(s): MONPHOBA

Model(s): Optical power range from -5,0 to +40,0 D in 0,5 D steps

Class: IIb

GMDN: 35658

Name: **monofocal toric yellow tinted
hydrophobic intraocular lens**

Trade name(s): MONPHOBA TORIC

Model(s): Optical power range from -5,0 to +40,0 D in 0,5 D steps
Cylinder range from 0,5 D to 6,0 D in 0,5 D steps

Class: IIb

GMDN: 35658

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Pollux Nova a.s.
U Křížku 572, 252 43 Průhonice, Czech Republic

Name: **monofocal yellow tinted hydrophobic
intraocular lens**

Trade name(s): MONPHOBA Q

Model(s): Optical power range from -5,0 to +40,0 D in 0,5 D steps

Class: IIb

GMDN: 35658

Name: **monofocal toric yellow tinted
hydrophobic intraocular lens**

Trade name(s): MONPHOBA TORIC Q

Model(s): Optical power range from -5,0 to +40,0 D in 0,5 D steps
Cylinder range from 0,5 D to 6,0 D in 0,5 D steps

Class: IIb

GMDN: 35658

Name: **trifocal yellow tinted hydrophobic
intraocular lens**

Trade name(s): TRIPHOPA Q

Model(s): Optical power range from -5,0 to +40,0 D in 0,5 D steps
Intermediate addition 1,8 D and near addition for
reading 3.5 D

Class: IIb

GMDN: 35658

Date: 2021-05-21
Revision: a



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issued for manufacturer:

Pollux Nova a.s.
U Křížku 572, 252 43 Průhonice, Czech Republic

Name: monoclonal yellow tinted extended
depth of focus hydrophobic intraocular
lens

Trade name(s): EDOPHOBA Q

Model(s): Optical power range from -5,0 to +40,0 D in 0,5 D steps

Class: IIb

GMDN: 35658

Facility(ies):

Pollux Nova a.s.
U Křížku 572, 252 43 Průhonice, Czech Republic (legal address)

Pollux Nova a.s.
U Gemini 360, 760 01 Zlín, Czech Republic (manufacturing site)



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issued for manufacturer:

Pollux Nova a.s.
U Křížku 572, 252 43 Průhonice, Czech Republic

Name: trifocal yellow tinted hydrophobic
intraocular lens

Trade name(s): TRIPHOPA

Model(s): Optical power range from -5,0 to +40,0 D in 0,5 D steps
Intermediate addition 1,8 D and near addition for
reading 3.5 D

Class: IIb

GMDN: 35658

Name: monoclinal yellow tinted extended
depth of focus hydrophobic intraocular
lens

Trade name(s): EDOPHOBA

Model(s): Optical power range from -5,0 to +40,0 D in 0,5 D steps

Class: IIb

GMDN: 35658

Name: monofocal clear hydrophobic
intraocular lens

Trade name(s): MONPHOBA CLEAR Q

Model(s): Optical power range from -5,0 to +40,0 D in 0,5 D steps

Class: IIb

GMDN: 35658

Date: 2021-05-21
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Certificate History:

Revision	Date	Reference Number	Action
	2020-09-30	803602844	Certification
a	2021-05-21	803602907	Adding new models



Date: 2021-05-21
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