

## QUALITY MANAGEMENT SYSTEM

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**EU-CERTIFICATE**

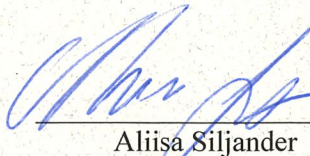
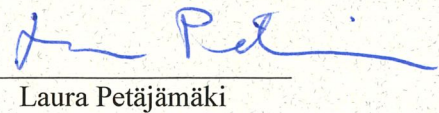
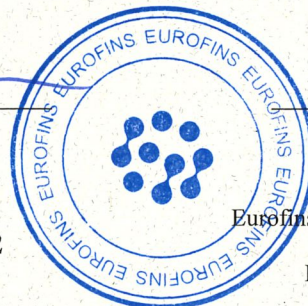
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## Regulation (EU) 2017/745

Manufacturer:	Pharmia Oy Kalliotie 2 04360 Tuusula Finland
Single registration number:	FI-MF-000001469
Conformity assessment procedure:	Regulation (EU) 2017/745 Annex IX
Device category:	MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route
Date of expiry:	30 November 2027

The manufacturer's quality management system covering the device category has been assessed and approved in accordance with the Annex IX to Regulation (EU) 2017/745. Approval shall be valid until the expiry date provided that the manufacturer fulfills the obligations imposed by Annex IX in Regulation. The products covered by the certificate and the details related to the maintenance of this certificate are specified in the attachment to the certificate.


Date of issue: 1 December 2022

  
Aliisa SiljanderCertificate no:  
**CR-03-1183-810-22**  
Laura PetäjämäkiNotified Body no. 0537:  
Eurofins Electric & Electronics Finland Oy  
Kivimiehentie 4  
FI-02151 Espoo, FINLANDInformation about the examinations and tests as per MDR Annex XII, section 10,  
is available upon request from [EES-medical@eurofins.fi](mailto:EES-medical@eurofins.fi).

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**Attachment 1 to the certificate no: CR-03-1183-810-22**


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<b>Manufacturer:</b>	Pharmia Oy Kalliotie 2 04360 Tuusula Finland	
<b>Other sites covered by the quality management system:</b>	-	
<b>Single registration number:</b>	FI-MF-000001469	
<b>Conformity assessment procedure:</b>	Regulation (EU) 2017/745 Annex IX	
<b>Limitations to the validity of the certificate:</b>	No limitations	

**The certificate covers the following products:**

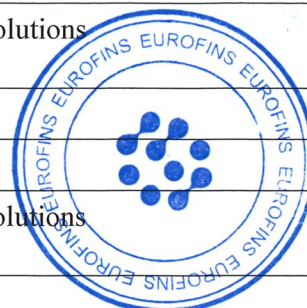
<b>MD-codes:</b>	MDN 1213 MDT 2006, MDT 2008, MDT 2011	
<b>Device category:</b>	MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	
<i>Product name</i>	<i>Product details</i>	
Aerose Moisturizing Nasal Spray	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	IIa
Metode+ Nesespray 100% Sesamolje	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	IIa
NASO seesamiöljy ratiopharm	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	IIa
Nosko Oil	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	IIa

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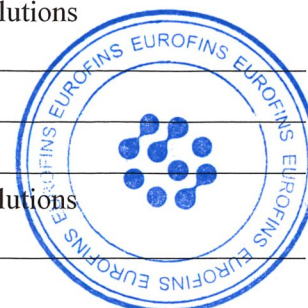

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Nozoil Aerazol do nosa	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	Ila
Nozoil Nasenspray	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	Ila
Nozoil Neussproei	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	Ila
Nozoil Original	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	Ila
Nozoil Original VN	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	Ila
Näsolja ABECE Nässpray	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	Ila
Näsolja Apofri Nässpray	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	Ila
Näsolja NET	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	Ila
Sanactiv Nasen-Pflegeöl	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	Ila



**Attachment 1 to the certificate no: CR-03-1183-810-22**

Sesam Olie Næsespray	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	IIa
ValMed næseolie/neseolje	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	IIa
NASO Fresh seesamiöljy ratiopharm	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	IIa
Aerose Plus Moisturizing Nasal Spray	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	IIa
FESS Dry Nose Oil	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	IIa
Flonase Nasal Spray, Mentol	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	IIa
Nozoil Menthol	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	IIa
Nozoil Neussproei Menthol	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	IIa
Näsolja Mentol ABECE Nässpray	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	IIa



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Näsölja Mentol Apofri	Model	-
	Nomenclature code	Q030103 Nasal irrigation solutions
	Risk class	Ila

The validity and maintenance of this certificate require the surveillance performed by the notified body in accordance with the MDR Annex IX (3). The surveillance includes annual quality management system audits at the manufacturer's premises as well as regular unannounced audits. If necessary, all audits may be carried out at the premises of the manufacturer's suppliers and/or subcontractors. The surveillance also includes the assessment of the significant changes planned by the manufacturer and the assessment of the technical documentation in accordance with the notified body's sampling plan (IIa and IIb).

Date of issue of this attachment: 1 December 2022



  
 Aliisa Siljander Laura Petäjämäki

Change history of the certificate:				
Certificate no	Revision	Status of the certificate	Date of issue	Description of the change
CR-03-1183-810-22	01	Initial certification	01.12.2022	Initial revision