Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 098084 0003 Rev. 01

Manufacturer:

Orantech Inc.
Zone#A, 4F
1st Bld, 7th Industrial Zone
Yulv Community, GongMing
Guangming New District
518106 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Spo2 Sensor, Temperature Probe, Fetal transducer and ETCO2 sensor**

The Certification Body of TÜV SÜD Product Service GmbH 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 subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: GZ1928002

Valid from: 2020-01-10
Valid until: 2024-05-26

Date, 2020-01-10

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Cojocaru Vera
Date: 2022.01.21 10:19:50 EET
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 098084 0003 Rev. 01

Facility(ies):

Orantech Inc.
Zone#A, 4F, 1st Bld, 7th Industrial Zone, Yulv Community,
GongMing, Guangming New District, 518106 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 098084 0004 Rev. 01

Holder of Certificate: **Orantech Inc.**
Zone#A, 4F
1st Bld, 7th Industrial Zone
Yulv Community, GongMing
Guangming New District
518106 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
Orantech Inc.
Zone#A, 4F, 1st Bld, 7th Industrial Zone, Yulv Community, GongMing, Guangming New District, 518106 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Spo2 Sensor, NIBP Cuff, Temperature Probe, ETCO2 Sensor, Fetal Transducer and Patient Cables and Leadwires**

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 098084 0004 Rev. 01

Report No.: GZ2028001

Valid from: 2020-09-05
Valid until: 2023-09-04

Date, 2020-08-19

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

CERTIFICAT ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ 認証書 ◆ CERTIFICATE ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 18 03 84065 005

Manufacturer:

Nuova GmbH
Lübecker Str. 17
23909 Ratzeburg
GERMANY

Facility(ies):

Nuova GmbH
Lübecker Str. 17, 23909 Ratzeburg, GERMANY

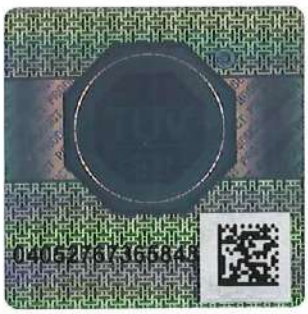
Product Category(ies):

Oxygen sensors

The Certification Body of TÜV SÜD Product Service GmbH 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 subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713129331

Valid from: 2018-06-18
Valid until: 2023-06-17



Date, 2018-04-18

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

EC CERTIFICATE

for the Quality Assurance System

according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

IT Dr. Gambert GmbH

Hinter dem Chor 21, 23966 Wismar, Germany

Certified location:

Hinter dem Chor 21, 23966 Wismar, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50403-Z6-00, the decision dated 2018-08-31 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2018-09-17 to 2023-09-16

Registration No.: 50403-16-07

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 • D-70565 Stuttgart

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-08-31
Notified Body ID-number: 0124

Annex to the EC Certificate No. 50403-16-07

Valid from 2018-09-17 to 2023-09-16

Revision status of the annex: 0 dated 2018-08-31

Devices/device categories included in the certificate:

Class II a:

- Oxygen sensors
- Nitric oxide sensors

DEKRA Certification GmbH
DEKRA Certification
D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2018-08-31
Notified Body ID-number: 0124

EG-Zertifikat / *EC-Certificate*

gem. 93/42/EWG Anhang II ohne (4) / *acc. 93/42/EEC Annex II without (4)*

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

Bıçakcılar Tıbbi Cihazlar Sanayi ve Ticaret A.Ş.
Osmangazi Mahallesi, Gazi Caddesi No: 21,
Esenyurt 34522 İstanbul
Türkiye

für die Produkte / die Kategorie: Liste der Produkte siehe Anlage 1
for the products / product category: List of products see annex 1

Medizinische Einmalartikel und Absauggeräte
Disposable medical devices and devices for aspiration and vacuum extraction

ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der genannten Produkte nach Maßgabe des Anhang II (ohne Abschnitt 4) der Richtlinie 93/42/EWG anwendet. Zusätzlich zur CE-Kennzeichnung muss die Kennummer der Benannten Stelle angebracht werden. Die Gültigkeit dieses Zertifikats beruht auf der Aufrechterhaltung des Qualitätssicherungssystems in Übereinstimmung mit den Anforderungen der Richtlinie und seiner Überwachung durch die Benannte Stelle gem. Anhang II Abschnitt 5. Das Zertifikat ist unter keinen Umständen übertragbar.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (without section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Reg.-Nr. / *Reg.-No.* 04 232 980886
Bericht Nr. / *Report No.* 3521 8285

Gültigkeit / *Validity*
von / *from* 2018-09-17
bis / *until* 2021-09-16
Edition 7

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-07-04

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Anlage 1, Blatt 1 von 7
Annex 1, page 1 of 7

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse III
Products of class III

Vent Catheter
Atrial Cannula
Vessel Cannula with / without check valve

Anmerkung: Für das Inverkehrbringen der in diesem Zertifikat genannten Klasse III Produkte wird eine gültige EG Auslegungsprüfbescheinigung gemäß MDD Anhang II (4) gefordert.
Note: *For the placing on the market of Class III devices covered by this certificate, a valid EC design-examination certificate according to MDD Annex II (4) is required.*

Bericht Nr. / *Report No.* 3521 8285

Gültigkeit / *Validity*
von / *from* 2018-09-17
Edition 12

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-08-03

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse IIb
Products of class IIb

Pressure Monitoring Set
Lekocyte Filter Set
Gamma Leukocyte Filter Set

Produkte der Klasse IIa
Products of class IIa

Thoracenthesis Set
Thoracic Catheter
Arterial Needle
Endotracheal Tube
Reinforced Endotracheal Tube
RAE Endotracheal Tube
Nasogastric Catheter
Stomach Catheter
Feeding Catheter
Manifold / Manifold Pressure
Three-Way Stopcock

Bericht Nr. / *Report No.* 3521 8285

Gültigkeit / *Validity*
von / *from* 2018-09-17
Edition 12

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-08-03

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse IIa
Products of class IIa

Tourniquet Set
IV Cannulae
Suction Catheter
Microaggregate Filter Set (Blood Filter Set)
Soft Drain
Oxygen Catheter
Nasal Oxygen Cannulae
Oxygen Connecting Tube
Tracheostomy Tube
Extracorporeal PVC Tubing
Extracorporeal Tubing Set
Quick Prime Set
Cardioplegia Set
Wound Drainage Set
Infusion Pump Set
Yankauer Suction Set
Suction Connecting Tube
Surgical Braided Tape
Nelaton Catheter
Tiemann Catheter

Bericht Nr. / *Report No.* 3521 8285

Gültigkeit / *Validity*
von / *from* 2018-09-17
Edition 12

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-08-03

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse IIa
Products of class IIa

Hydrophilic coated uretheral Catheter
IV Filter Set
Aspirators
Blood Transfusion Set
Rectal Catheter
Umbilical Catheter
Angiographic Kit
B-Soft Kit
Aortic Punch
Gas Sampling Line

Bericht Nr. / *Report No.* 3521 8285

Gültigkeit / *Validity*
von / *from* 2018-09-17
Edition 12

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-08-03

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse Is (steril)
Products of class Is (sterile)

Urine Collection Bag
Pleural Drainage Set
Central Venous Pressure Set
Guedel Airway
Spigot
Extension Lines
Kapkon Connector
Straight Connector
Straight Luer Connector
Y Connector
Y Luer Connector
Stopper
Instopper
Umbilical Cord Clamp
T.U.R. Set / Arthroscopy set
Transfer Set
Intravenous Infusion Sets
Intravenous Infusion Sets / Flowmeter
Intravenous Infusion Sets / Burette

Bericht Nr. / *Report No.* 3521 8285

Gültigkeit / *Validity*
von / *from* 2018-09-17
Edition 12

M2.98

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-08-03

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse Is (steril)
Products of class Is (sterile)

B-Safe
Intubation Stylet
Combi Stopper
Urimeter
Thoracic Drainage Set
Vaginal Specula
ENEMA Set
I.V. Infusion Set w/B-Flow Flow Regulator
Control Syringe
Meconium Aspiration Connector

Anmerkung: Für Produkte der Klasse I steril beschränkt sich das Zertifizierungsverfahren auf die Aspekte der Herstellungsschritte in Zusammenhang mit der Sterilisation und der Aufrechterhaltung der Sterilität.
Note: *For products of class I sterile the certification process is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.*

Bericht Nr. / *Report No.* 3521 8285

Gültigkeit / *Validity*
von / *from* 2018-09-17
Edition 12

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-08-03

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse Im (mit Messfunktion)
Products of class Im (with measuring function)

Urimeter
C.V.P. Set
Pleural Drainage Set
Volumetric Exerciser (B-Spiro)
Infusion Set w/Burette
Thoracic Drainage Set

Anmerkung: Für Produkte der Klasse I mit Messfunktion beschränkt sich das Zertifizierungsverfahren auf die Herstellungsschritte in Zusammenhang mit der Konformität der Produkte mit den messtechnischen Anforderungen.
Note: *For products of class I with measuring functions the certification process is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.*

Bericht Nr. / *Report No.* 3521 8285

Gültigkeit / *Validity*
von / *from* 2018-09-17
Edition 12

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-08-03

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2018 *Version number 3* *Revision: 26.06.2018*

*

SECTION 1: Identification of the substance/mixture and of the company/undertaking

· ***1.1 Product identifier***

· ***Trade name:*** **Grafitpaste "Nivo"**
Grafitose-Flexoperm

· ***UFI-Code:*** UD10-80TP-V00M-EFMJ

· ***1.2 Relevant identified uses of the substance or mixture and uses advised against***
No further relevant information available.
· ***Application of the substance / the mixture*** Lubricant

· ***1.3 Details of the supplier of the safety data sheet***
· ***Manufacturer/Supplier:***
Fermit GmbH
Zur Heide 4,
D- 53560 Vettelschoß
www.fermit.de

· ***Informing department:***
Tel.: +49 (0) 2645-2207
Fax: +49 (0) 2645-3113
Email: info@fermit.de

· ***1.4 Emergency telephone number:*** Tel.: +49 (0) 2645-2207

SECTION 2: Hazards identification

· ***2.1 Classification of the substance or mixture***
· ***Classification according to Regulation (EC) No 1272/2008***
The product is not classified, according to the CLP regulation.

· ***2.2 Label elements***
· ***Labelling according to Regulation (EC) No 1272/2008*** Void
· ***Hazard pictograms*** Void
· ***Signal word*** Void
· ***Hazard statements*** Void
· ***2.3 Other hazards***
· ***Results of PBT and vPvB assessment***
· ***PBT:*** Not applicable.
· ***vPvB:*** Not applicable.

SECTION 3: Composition/information on ingredients

· ***3.2 Chemical characterisation: Mixtures***
· ***Description:*** Mixture consisting of mineral oil and graphite.

· ***Dangerous components:*** Void
· ***Additional information*** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

· ***4.1 Description of first aid measures***
· ***General information*** Instantly remove any clothing contaminated by the product.
· ***After inhalation*** Supply fresh air; consult doctor in case of symptoms.
· ***After skin contact***
Instantly wash with water and soap and rinse thoroughly.

(Contd. on page 2)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2018 *Version number 3* *Revision: 26.06.2018*

Trade name: **Grafitpaste "Nivo"**
Grafitose-Flexoperm

(Contd. from page 1)

If skin irritation continues, consult a doctor.
· ***After eye contact***
Keep eye lids open and rinse them with ample amounts of clean running water for at least 15 minutes.
Seek medical treatment.
· ***After swallowing*** Do not induce vomiting; instantly call for medical help.
· ***4.2 Most important symptoms and effects, both acute and delayed***
No further relevant information available.
· ***4.3 Indication of any immediate medical attention and special treatment needed***
No further relevant information available.

SECTION 5: Firefighting measures

· ***5.1 Extinguishing media***
· ***Suitable extinguishing agents***
Extinguishing powder, foam or water jet. Fight larger fires with water jet or alcohol-resistant foam.
· ***For safety reasons unsuitable extinguishing agents*** Water with a full water jet.
· ***5.2 Special hazards arising from the substance or mixture***
Formation of toxic gases is possible during heating or in case of fire.
Can be released in case of fire:
Carbon monoxide (CO)
· ***5.3 Advice for firefighters***
· ***Protective equipment:*** Do not inhale explosion gases or combustion gases.

SECTION 6: Accidental release measures

· ***6.1 Personal precautions, protective equipment and emergency procedures***
The usual precautionary measures should be adhered to general rules for handling chemicals.
Ensure adequate ventilation
· ***6.2 Environmental precautions:***
Prevent from spreading (e.g. by damming-in or oil barriers).
Inform respective authorities in case product reaches water or sewage system.
Do not allow to enter drainage system, surface or ground water.
· ***6.3 Methods and material for containment and cleaning up:***
Remove from the surface of water (e.g. skim or vacuum off)
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders).
Send for recovery or disposal in suitable containers.
· ***6.4 Reference to other sections***
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for information on disposal.

SECTION 7: Handling and storage

· ***7.1 Precautions for safe handling***
No special precautions necessary if used correctly.
Avoid direct contact with eyes, skin and clothing.
· ***Information about protection against explosions and fires:*** No special measures required.

· ***7.2 Conditions for safe storage, including any incompatibilities***
· ***Storage***
· ***Requirements to be met by storerooms and containers:*** Store only in the original container.
· ***Information about storage in one common storage facility:***
Keep away from strong oxidizing, alkalis and acidic materials.

(Contd. on page 3)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2018 *Version number 3* *Revision: 26.06.2018*

Trade name: **Grafitpaste "Nivo"**
Grafitose-Flexoperm

(Contd. from page 2)

· ***Further information about storage conditions:*** Protect from heat and direct sunlight.
· ***7.3 Specific end use(s)*** No further relevant information available.

SECTION 8: Exposure controls/personal protection

· ***8.1 Control parameters***
· ***Components with limit values that require monitoring at the workplace:***
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· ***Additional information:*** The lists that were valid during the compilation were used as basis.

· ***8.2 Exposure controls***
· ***Personal protective equipment***
· ***General protective and hygienic measures***
Avoid close or long term contact with the skin.
Do not carry cleaning cloths impregnated with the product in trouser pockets.
The usual precautionary measures should be adhered to general rules for handling lubricants.
· ***Breathing equipment:***
Not required.
Use breathing protection only when aerosol or mist is formed.
· ***Protection of hands:***
In case of longer or repeated contact with the skin: use protective cream for the skin surfaces coming into contact with the product.
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
· ***Material of gloves***
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
· ***Penetration time of glove material***
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· ***For the permanent contact gloves made of the following materials are suitable:***
Nitrile rubber, NBR
· ***Eye protection:*** Safety glasses recommended during refilling.
· ***Body protection:*** Protective work clothing.

SECTION 9: Physical and chemical properties

· ***9.1 Information on basic physical and chemical properties***
· ***General Information***
· ***Appearance:***

Form:	Liquid
Colour:	Black
· ***Odour:***	odourless

· ***Change in condition***	
Melting point/freezing point:	Not determined
Initial boiling point and boiling range:	Not determined

· ***Flash point:***	320 ℃ Mineral oil

(Contd. on page 4)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2018 *Version number 3* *Revision: 26.06.2018*

Trade name: **Grafitpaste "Nivo"**
Grafitose-Flexoperm

(Contd. from page 3)

· ***Self-inflammability:***	Product is not selfigniting.
· ***Explosive properties:***	Product is not explosive.
· ***Density***	Not determined
· ***Solubility in / Miscibility with Water:***	Insoluble
· ***Solvent content:***	
Water:	0.0 %
· ***9.2 Other information***	No further relevant information available.

SECTION 10: Stability and reactivity

· ***10.1 Reactivity*** No further relevant information available.
· ***10.2 Chemical stability***
· ***Thermal decomposition / conditions to be avoided:***
No decomposition if used according to specifications.
· ***10.3 Possibility of hazardous reactions*** No dangerous reactions known
· ***10.4 Conditions to avoid*** No further relevant information available.
· ***10.5 Incompatible materials:*** Avoid contact with strong oxidizing agents.
· ***10.6 Hazardous decomposition products:***
None in case of intended use and storage in compliance with instructions.

SECTION 11: Toxicological information

· ***11.1 Information on toxicological effects***
· ***Acute toxicity*** Based on available data, the classification criteria are not met.
· ***Primary irritant effect:***
· ***Skin corrosion/irritation***
More frequent and continuous contact with the skin may result in irritation of the skin.
Longer or repeated contact with the product reduces the natural readipogenesis of the skin and results in the desiccation of the skin. That product can be absorbed via the skin.
· ***Serious eye damage/irritation*** Not determined.
· ***Respiratory or skin sensitisation*** Based on available data, the classification criteria are not met.
· ***CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)***
· ***Germ cell mutagenicity*** Based on available data, the classification criteria are not met.
· ***Carcinogenicity*** Based on available data, the classification criteria are not met.
· ***Reproductive toxicity*** Based on available data, the classification criteria are not met.
· ***STOT-single exposure*** Based on available data, the classification criteria are not met.
· ***STOT-repeated exposure*** Based on available data, the classification criteria are not met.
· ***Aspiration hazard*** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· ***12.1 Toxicity***
· ***Aquatic toxicity:*** No further relevant information available.
· ***12.2 Persistence and degradability*** No further relevant information available.
· ***Other information:*** The product is slightly biodegradable.
· ***12.3 Bioaccumulative potential*** No further relevant information available.
· ***12.4 Mobility in soil*** No further relevant information available.

(Contd. on page 5)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2018 *Version number 3* *Revision: 26.06.2018*

Trade name: **Grafitpaste "Nivo"**
Grafitose-Flexoperm

(Contd. from page 4)

· ***Additional ecological information:***
· ***General notes:***
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.
· ***12.5 Results of PBT and vPvB assessment***
· ***PBT:*** Not applicable.
· ***vPvB:*** Not applicable.
· ***12.6 Other adverse effects*** No further relevant information available.

SECTION 13: Disposal considerations

· ***13.1 Waste treatment methods***
· ***Recommendation***
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
The waste code numbers mentioned are recommendations based on the probable use of the product.

· ***European waste catalogue***	
13 00 00	OIL WASTES AND WASTES OF LIQUID FUELS (except edible oils, and those in chapters 05, 12 and 19)
13 02 00	waste engine, gear and lubricating oils
13 02 05*	mineral-based non-chlorinated engine, gear and lubricating oils
12 00 00	WASTES FROM SHAPING AND PHYSICAL AND MECHANICAL SURFACE TREATMENT OF METALS AND PLASTICS
12 01 00	wastes from shaping and physical and mechanical surface treatment of metals and plastics
12 01 12*	spent waxes and fats

· ***Uncleaned packagings:***
· ***Recommendation:*** Non contaminated packagings can be used for recycling.

SECTION 14: Transport information

· ***14.1 UN-Number***	
· ***ADR, ADN, IMDG, IATA***	Void
· ***14.2 UN proper shipping name***	
· ***ADR, ADN, IMDG, IATA***	Void
· ***14.3 Transport hazard class(es)***	
· ***ADR, ADN, IMDG, IATA***	
· ***Class***	Void
· ***14.4 Packing group***	
· ***ADR, IMDG, IATA***	Void
· ***14.5 Environmental hazards:***	
· ***Marine pollutant:***	No
· ***14.6 Special precautions for user***	Not applicable.

(Contd. on page 6)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2018 *Version number 3* *Revision: 26.06.2018*

Trade name: **Grafitpaste "Nivo"**
Grafitose-Flexoperm

(Contd. from page 5)

· ***14.7 Transport in bulk according to Annex II of Marpol and the IBC Code***	Not applicable.
· ***Transport/Additional information:***	Not dangerous according to the above specifications.
· ***UN "Model Regulation":***	Void

SECTION 15: Regulatory information

· ***15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture***

· ***Directive 2012/18/EU***
· ***Named dangerous substances - ANNEX I*** None of the ingredients is listed.

· ***National regulations***

· ***Water hazard class:*** Water hazard class 1 (Self-assessment): slightly hazardous for water.

· ***Substances of very high concern (SVHC) according to REACH, Article 57***
None of the ingredients is contained.

· ***15.2 Chemical safety assessment:*** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· ***Department issuing data specification sheet:***
This Material Safety Data Sheet has been drawn up in cooperation with:
DEKRA Assurance Services GmbH, Hanomagstr. 12, D-30449 Hanover, Germany,
phone: (+49) 511 42079 - 0, reach@dekra.com.

· ***Abbreviations and acronyms:***
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
SVHC: Substances of Very High Concern
vPvB: very Persistent and very Bioaccumulative

· **** Data compared to the previous version altered.***