CISQ is a member of

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

ICIM

CERTIFICATO n.
CERTIFICATE No. **4265/4/C**

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

KIMA S.R.L.

UNITÀ OPERATIVE / *OPERATIVE UNITS*

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 29

Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.

Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

Data emissione	Emissione corrente	Data di scadenza
First issue	*Current issue*	*Expiring date*
18/01/2007	18/01/2019	17/01/2022

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

Digitally signed by Ceaicovschi Tudor
Date: 2021.11.30 16:42:27 EET
Reason: MoldSign Signature
Location: Moldova

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.

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

0860CM_02_IT

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ICIM

CERTIFICATO n. / *CERTIFICATE No.* **4264/4/C**

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

KIMA S.R.L.

UNITÀ OPERATIVE / *OPERATIVE UNITS*

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI EN ISO 9001:2015

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Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

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0449CM_03_IT

data 27/09/2021

DICHIARAZIONE DI CONFORMITÁ CE
EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CE *Dispositivi Medico-Diagnostici In Vitro e s.m.i.*
according to Annex III of the Directive 98/79/EC In Vitro Diagnostic Medical Devices as amended.

fabbricante
manufacturer

ROLL S.r.l.
- ***articoli per laboratori analisi - disposable labware***

indirizzo
address

Via Leonardo da Vinci, 24/a
35028 Piove di Sacco (PD) - Italia

telefono *phone* ***+39-049-9719511***
fax *fax* ***+39-049-9719542***
posta elettronica *e-mail* **roll@tecnomeus.it**

Identificazione dei prodotti **ANSE IN POLISTIROLO DA 10 MICROLITRI STERILI CF. 20 PZ**

product identification **STERILE LOOPS 10 UL - IN BAGS OF 20 PCS**

numero di catalogo *part number* **18288**
numero di lotto *batch number* **115B23**
scadenza *expiry date* **31/03/2026**

classificazione dei prodotti *product identification* **dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE e s.m.i.**
devices other then those mentioned in Annex II of the Directive 98/79/EC as amended

Si dichiara
sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i. *Dispositivi Medico–Diagnostici In Vitro.*

Tutta la documentazione tecnica richiesta dall'Allegato III della succitata Direttiva, e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, sono conservati a cura del Fabbricante

Hereby we declare
under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 98/79/EC as amended on In Vitro Diagnostic Medical Devices.

All the supporting documents, as required by Annex III of the 98/79/EC Directive, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data
place and date

Piove di Sacco, 27/09/2021 (data di stampa)

firma
signature

ROLL S.r.l.
Assicurazione Qualità

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

№ 005032

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер № 04EAC1.CM.03842

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

105173, Россия, г. Москва, ул. Главная, д. 6, кв. 12

(юридический адрес лица)

143906, Россия, Московская область, г. Балашиха, квартал Щитниково, д. 88А

(фактический адрес лица)

ИНН: 7719187311 **ОГРН: 1037739078970**

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ СООТВЕТСТВИЕ

системы менеджмента качества изделий медицинских Общества с ограниченной ответственностью «Агат-Мед» требованиям ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования» применительно к разработке, производству и продаже медицинских изделий для in vitro диагностики: реагентов и наборов реагентов для клинической биохимии, а также калибраторов и контрольных материалов

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии _____ (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

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ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

РАЗРЕШЕНИЕ
на применение знака соответствия системы добровольной сертификации ГОСТ Р «EAC AUDIT»

Регистрационный номер № 04EAC1.CM.03842

ВЫДАНО НА ОСНОВАНИИ РЕШЕНИЯ О ВЫДАЧЕ СЕРТИФИКАТА СООТВЕТСТВИЯ СИСТЕМЫ МЕНЕДЖМЕНТА КАЧЕСТВА ИЗДЕЛИЙ МЕДИЦИНСКИХ

Общество с ограниченной ответственностью «Агат-Мед»

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(фактический адрес лица)

ИНН: 7719187311 **ОГРН: 1037739078970**

РАЗРЕШАЕТ

Применять знак соответствия системы добровольной сертификации «EAC AUDIT» на период действия сертификата соответствия № 04EAC1.CM.03842 в любой форме, исключающей возможность толкования его как знака соответствия качества продукции. Допускается использовать знак соответствия в рекламных буклетах, проспектах, брошюрах, плакатах, бланках организационно-распорядительной документации организации – держателя сертификата.

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: _____ (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

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Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-02

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Гладун Виталий Викторович

соответствует требованиям системы добровольной сертификации «EAC AUDIT», предъявляемым к аудиторам внутренних проверок системы менеджмента качества изделий медицинских на соответствие стандарту ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования»

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: _____ (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

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СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-03

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Нефуков Юрий Николаевич

соответствует требованиям системы добровольной сертификации «EAC AUDIT», предъявляемым к аудиторам внутренних проверок системы менеджмента качества изделий медицинских на соответствие стандарту ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования»

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Председатель экспертной комиссии: Курбатова (подпись) **Е. Д. Курбатова**

М.П.

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Certificate Of Analysis

(Analysenzertifikat)

HOLTSCH
Medizinprodukte GmbH

Product / Lot-No. (Produkt / Ch.bez.) :	*Quickpad*	*060321*
Date of Manufacturing (Herstellungsdatum):	*02.03.-09.03.2021*	
Expiry Date (Verfallsdatum) :	*02/2023*	

	Specification (Spezifikation)	**Result** (Ergebnis)
Description (Beschreibung) :	milky-white to yellowish transparent plastic container, filled with white and separately detachable non-woven pads and isopropanol 70% /V/V) Milchig-weiße bis leicht gelbliche, durchsichtige Kunststoffdose, befüllt mit weißen, einzeln abreißbaren Vliestupfern und Isopropanol 70% (V/V)	*complies (entspricht)*
Leak tightness and intactness of container (Dichtigkeit und Unversehrtheit des Behältnisses) :	fully welded and intact vollständig verschweißt und unversehrt	*complies (entspricht)*
Sterility (Sterilität):	sterile (steril)	*complies (entspricht)* [1]

[1] The sterility of product is ensured by the process of irradiation and is tested only at randoms intervalls.
Die Sterilität des Produktes wird durch den Bestrahlungsprozess sichergestellt und nur stichprobenartig geprüft.

Summary (Gesamtbeurteilung):
The above mentioned lot complies with the specification.
Die o.g. Charge entspricht der Spezifikation.

Comments (Bemerkungen): *none (keine)*

Date / Signature Head of Quality Control:
(Datum / Unterschrift Leiter Qualitätskontrolle)

25.06.21 Wiehe

Zertifikat Protokoll **BESTRAHLUNG**

certificate protocol **IRRADIATION**

Auftragsnummer (AN) : 181184/2021
order number (internal)

Kundennummer : 728
Customer number

DB Nr	181184
BP Nr	239.691

Synergy Health Radeberg GmbH; Juri-Gagarin-Str.15;01454 Radeberg

Auftraggeber (Customer)	Auftragnehmer (performer)
Holtsch Medizinprodukte GmbH Leipziger Str. 300 **01139 Dresden**	Synergy Health Radeberg GmbH Juri-Gagarin-Str.15 **01454 Radeberg** Tel.: +49 3528 / 4364 - 16 Fax: +49 3528 / 4364 - 99

Auftragsnummer (AG) : 20.30.2021
order number Customer

Auftragsdatum : 30.03.2021
date of order

Name des Produktes : Quickpad (Kosmetik)
name of product

Artikelcode :
item code

Charge : 060321, Vref.: 02.2023
batch number

Bestrahlungszyklus : A-14p/21
irradiation cycle

Spezifikation : DD0728_0440_2020_R34
specification

Bestrahlungsdatum : 11.04.2021
irradiation date

Identifikationsnummer : 845555 - 845558
identification number

Bestrahlungseinheiten : EP-Palette
irradiation unit

Anzahl : 4
quantity

Verpackungseinheiten : Palette
packaging unit

Anzahl : 2
quantity

Besonderheiten :
remarks

Die Bestrahlung erfolgt gemäß AAMI TIR33 / ISO 11137 und Produktspezifikation.
The irradiation has been performed in accordance to AAMI TIR33/ ISO 11137 as well as to product specification.

Dosis dose	Energiedosis laut Auftrag dose in accordance with order	Dosimetrisch ermittelte Dosis calculated dose	Identnummer : identification number
min. Dosis: minimum dose	25,0 kGy	28,11 kGy	845558
max. Dosis: maximum dose	40,0 kGy	36,20 kGy	845557

Unterbrechungszeit >24 h : Nein
interruption time over 24 hours

Anlage : GS3000
(facility)

Strahlungsart : Co-60
(kind of radiation)

Erstellung und Datenübernahme
preparation and data transfer

13.04.2021

Datum und Unterschrift Ersteller
date and signature originator

Freigabe des oben genannten Bestrahlungsgutes zur Auslieferung
Release of specified product for delivery

13.04.2021

Datum und Unterschrift Qualität
date and signature quality

Protokollsignatur 83adfc25e4a38187c9e5292ff18c471f

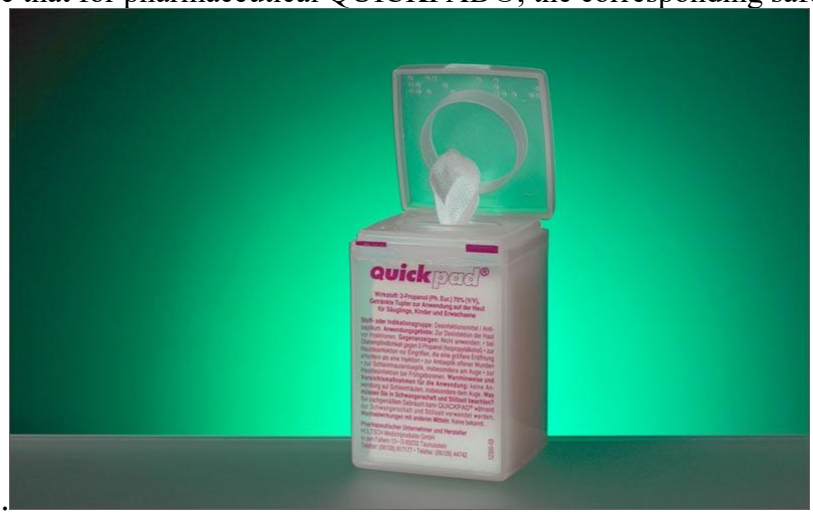
Alcohol Swab Dispenser QUICKPAD®

Practical and efficient

The QUICKPAD® alcohol swab dispenser, being sterile and physiologically verified as harmless, is ideal for cleaning and disinfecting the skin. The active agent 2-propanol acts as an effective, "mild on skin" disinfecting agent. The patented "swab tear-off" system allows for the single use of the swab. This makes QUICKPAD® not only economical but also efficient in its use.

Quality and Endurance

The lid of the QUICKPAD® alcohol swab dispenser container seals air-tight, keeping the alcohol swabs moist and sterile. As a result, the swab dispenser has a particularly long shelf life of 24 months.

Please note that for pharmaceutical QUICKPAD®, the corresponding safety instruction is applicable. 

Characteristics

- Single swab tear-off system allows for an efficient and economical use
- Fill Level control due to transparent container
- Retains moisture and sterility
- Physiologically harmless non-woven swab

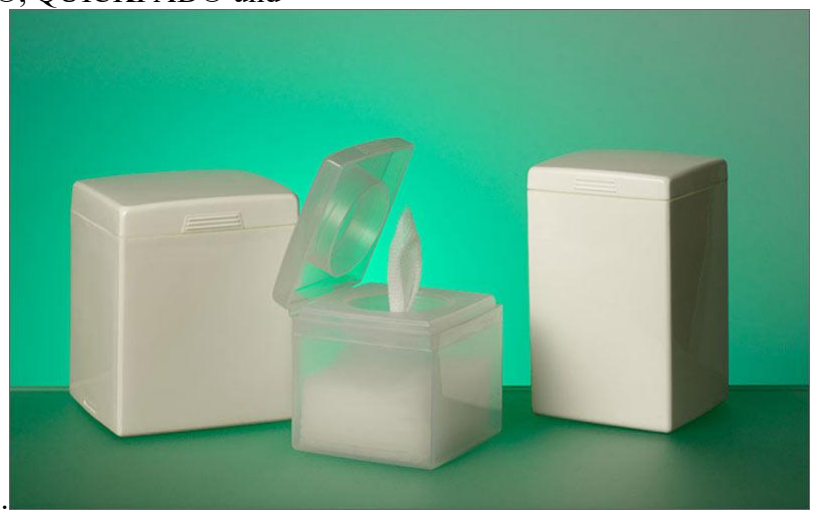
- Available in three practical sizes (only as cosmetic)
- Suitable for self-application by the patient
- Ready for use
- Made in Germany Quality, CE Label

Range of Application

QUICKPAD® is supplied ready for use and with its simple operation, can be used by specialists as well as patients for disinfecting the skin. An ideal product for diabetics and other users of subcutaneous self-injection syringes.

Product range

The Quickpad® swap dispenser is available is available in three different sizes, MINIPAD®, QUICKPAD® und BIGPAD®.



	MINIPAD®	QUICKPAD®	BIGPAD®
size dispencer (L x W x H in mm)	50 x 50 x 50	**50 x 50 x 80**	62 x 62 x 75
Number of swabs per dispencer	50	**150**	100
size swabs(L x B in mm)	44 x 44	**44 x 44**	58 x 58

LANDESDIREKTION
SACHSEN

Freistaat
SACHSEN

Zertifikat-Nr./Certificate no:
DE_SN_01_GMP_2020_0038

Aktenzeichen/Reference Number:
26-5117/90

BESTÄTIGUNG DER ÜBEREINSTIMMUNG EINES HERSTELLERS MIT GMP

Teil 1

Ausgestellt nach einer Inspektion gemäß

- **Art. 111 (5) der Richtlinie 2001/83/EG**

Die zuständige deutsche Überwachungsbehörde bestätigt:

Der Hersteller
HOLTSCH Medizinprodukte GmbH

Anschrift der Betriebsstätte
HOLTSCH Medizinprodukte GmbH
Leipziger Straße 300
01139 Dresden
Deutschland

- wurde im Rahmen der nationalen Arzneimittelüberwachung inspiziert in Verbindung mit der Herstellungserlaubnis Nr. DE_SN_01_MIA_2016_0010 gemäß
  - Art. 40 der Richtlinie 2001/83/EG

umgesetzt in deutsches Recht durch:
§ 13 Abs. 1 und § 72 Arzneimittelgesetz

Aufgrund der aus der letzten Inspektion vom 24. Januar 2019 gewonnenen Erkenntnisse wird für die oben genannte Betriebsstätte des Herstellers die Übereinstimmung mit den Anforderungen der Guten Herstellungspraxis festgestellt, die sich aus

- den Grundsätzen und Leitlinien der Guten Herstellungspraxis gemäß
  - Richtlinie 2003/94/EG

ergeben.

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with

- **Art. 111 (5) of Directive 2001/83/EC**

The competent authority of GERMANY confirms the following:

The manufacturer
HOLTSCH Medizinprodukte GmbH

Site address
HOLTSCH Medizinprodukte GmbH
Leipziger Straße 300
01139 Dresden
Germany

- has been inspected under the national inspection programme in connection with manufacturing authorisation no. DE_SN_01_MIA_2016_0010 in accordance with
  - Art. 40 of Directive 2001/83/EC

transposed in the following national legislation:
Sect 13 para 1 and sect 72 Arzneimittelgesetz (German Drug Law)

From the knowledge gained during the inspection of this manufacturer, the latest of which was conducted on 24 January 2019, it is considered that it complies with the Good Manufacturing Practice requirements referred to in

- the principles and guidelines of Good Manufacturing Practice laid down in
  - Directive 2003/94/EC

Dieses Zertifikat bestätigt den Status der Betriebsstätte zum Zeitpunkt der oben genannten Inspektion. Es sollte nicht zur Bestätigung der Übereinstimmung herangezogen werden, wenn seit der genannten Inspektion mehr als drei Jahre vergangen sind. Nach Ablauf dieser Zeit sollte mit der zuständigen Behörde Kontakt aufgenommen werden. Das Zertifikat ist nur bei Vorlage sämtlicher Seiten inklusive der Teile 1 und 2 gültig. Die Echtheit dieses Zertifikates kann ggf. durch die ausstellende Behörde bestätigt werden.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted. This certificate is valid only when presented with all pages and both parts 1 and 2. The authenticity of this certificate may be verified with the issuing authority.

Teil 2

• Humanarzneimittel

1 HERSTELLUNGSTÄTIGKEITEN

1.1 Sterile Produkte

1.1.2 Im Endbehältnis sterilisiert (Herstellungstätigkeiten für folgende Darreichungsformen)

1.1.2.5 Andere endsterilisierte Produkte
Alkoholtupfer

1.1.3 Chargenfreigabe

28. September 2020

Name und Unterschrift des Bearbeiters der zuständigen Behörde

Klaus Hartmann
Landesdirektion Sachsen
Referat 26 Pharmazie, GMP-Inspektorat
Braustraße 2
04107 Leipzig
Deutschland

Tel.: +49(0)351 825-2411
Fax: +49(0)351 825-9201

Part 2

• Human Medicinal Products

1 MANUFACTURING OPERATIONS

1.1 Sterile Products

1.1.2 Terminally sterilised (processing operations for the following dosage forms)

1.1.2.5 Other terminally sterilised prepared products
alcoholic pads

1.1.3 Batch certification

28 September 2020

Name and signature of the authorised person of the Competent Authority

Klaus Hartmann
Landesdirektion Sachsen
Referat 26 Pharmazie, GMP-Inspektorat
Braustraße 2
04107 Leipzig
Deutschland

Tel.: +49(0)351 825-2411
Fax: +49(0)351 825-9201

LANDESDIREKTION SACHSEN
09105 Chemnitz

MANUFACTURER'S AUTHORISATION

(This English translation is for reference only. It is not part of the official certificate.)

1. Authorisation number/file number	DE_SN_01_MIA_2012_0045/Nr. 6 / 24-5482.11/62
2. Name of authorisation holder	HOLTSCH Medizinprodukte GmbH
3. Address(es) of manufacturing site(s)	HOLTSCH Medizinprodukte GmbH Leipziger Straße 300 01139 Dresden
4. Legally registered address of authorisation holder	In den Faltern 13 65232 Taunusstein
5. Scope of authorisation and dosage forms	ANNEX 1
6. Legal basis of authorisation	Sect 13 para 1 Arzneimittelgesetz (German Drug Law)
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Edith Detlefsen
8. Signature	
9. Date	09/27/2012
10. Annexes attached	Annex 1 Annex 4 (Addresses of Contract Laboratories) Annex 5 (Name of Qualified Person) Annex 7 (Date of inspection on which authorisation granted, scope of last inspection) Annex 8 (Manufactured/ imported products authorised)

FREISTAAT SACHSEN LANDESDIREKTION SACHSEN

SCOPE OF AUTHORISATION **Annex 1**

Name and address of the site:
HOLTSCH Medizinprodukte GmbH, Leipziger Straße 300, 01139 Dresden

Human Medicinal Products

AUTHORISED OPERATIONS
Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;

- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;

- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form (applicable to all sections of Part 1 apart from sections 1.5.2 and 1.6)

1.1	**Sterile Products**
	1.1.3 Batch certification only
1.2	**Non-sterile products**
	1.2.1 Non-sterile products
	1.2.1.17 Other non-sterile medicinal product alcoholic pads

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

This Authorisation is according with the site plans of manufacturing rooms with list of room numbers and classification dated 16 July,2009.

Address(es) of Contract Laboratories	Li-iL GmbH Arzneimittel Arzneibäder Leipziger Strasse 300 01139 Dresden - total quality control without sterility and microbiological testing
	SGS Institut Fresenius GmbH Im Maisel 14 65232 Taunusstein - Sterility Testing in accordance with Pharm Europ. 2.6.1 - Microbiological Testing non-steril products in accordance with Pharm Europ. 2.6.12 Total viable aerobic count of non-sterile intermediate

Name(s) of Qualified Person(s)	Mrs. Dr. Karin Beck-Piotraschke
	Mr. Malte Hertzberg

Date of Inspection on which authorisation was granted	09/01/2011
Scope of last Inspection	Quality Management, Personnel, Premises and Equipment, Documentation, Contract Manufactore and Analysis, Complaints and Product Recall, Self Inspection

Annex 8

Products authorised to be manufactured/imported (in accordance with Article 41 and 42 of Directive 2001/83/EC and/or Article 45 and 46 of Directive 2001/82/EC, as amended).

Quickpad® Tupfer

FREISTAAT SACHSEN LANDESDIREKTION SACHSEN

HOLTSCH Medizinprodukte GmbH
In den Faltern 13 • D – 65232 Taunusstein
Germany

Declaration of conformity

This is to confirm that

the swab dispenser **Quickpad®**
containing fleece swabs, saturated with 70% isopropyl alcohol (V/V)

is

manufactured, packaged and sterilized in accordance with the rules of GMP and the paragraph 13 of the GERMAN MEDICAL LAW.

These swabs are equal to a
Medical Device Class I (UMNDS Code15-252)
and are checked and released

conform to

the German Medical Product Law according to

the
Medical Device Directive 93/42/EEC
of the European Counsel.

Taunusstein, November 17th , 2021

HOLTSCH Medizinprodukte GmbH

HOLTSCH
Medizinprodukte GmbH
In den Faltern 13 · 65232 Taunusstein

Malte Hertzberg
(Certified Biologist)

***HOLTSCH* Medizinprodukte GmbH**
D 65323 Taunusstein • Germany

To whom it may concern

The product line of our swab dispenser is ruled differently according to the claim which is posted on the product. In Germany both is possible.
It depends on the claim you choose. If the claim is for **disinfecting** the skin before an injection, etc, it is ruled by the **AMG** (German Drug Law). If we sell Quickpad just for **cleaning** the skin Quickpad is ruled as a **cosmetic** (for example like make up remover).

We produce and sell „Quickpad" in Germany under the regulations of the German Drug Law (Arzneimittelgesetz **AMG**).
The European market and the European regulations (i.e. Guideline-for medical items-93/42/EWG), are converted in Germany into the Medizinproduktegesetz (**MPG**).

There is a difference between these two regulations.
The **AMG** (strictly national) covers all products which have a pharmaceutical effect.
The **MPG** covers all products which are not drugs but support drugs or have a **physical** (not a pharmaceutical) effect, like for example our tourniquet. The MPG fulfils the guideline 93/42/EWG. MPG, items have to bear the CE signet.

As mentioned before it depends on the claim you choose. If the claim is for disinfecting the skin before an injection, etc., it is a drug and ruled by the AMG. For this reason we have the permission to produce and to market this product under AMG (CE-signet is not possible in this case). The product has to be labeled strictly with the original HOLTSCH label

If your claim is for **cleaning** the skin, it is considered as a cosmetic item and is ruled by the cosmetic act and has no CE signet and no special permission as per the AMG is necessary. This is also possible in Germany.

Most of our customers do not declare Quickpad as a drug because they might run through some kind of registration with their ministry of health. They prefer to use Quickpad like a cosmetic and as explained above there is no possibility of a CE-signet on the product.
Maybe the regulations in other countries are different.

If so, please let us know.

Taunsstein, September 07, 2021

Malte Hertzberg
Qualified Person AMG

HOLTSCH MED

Quality. Safety. Trust.

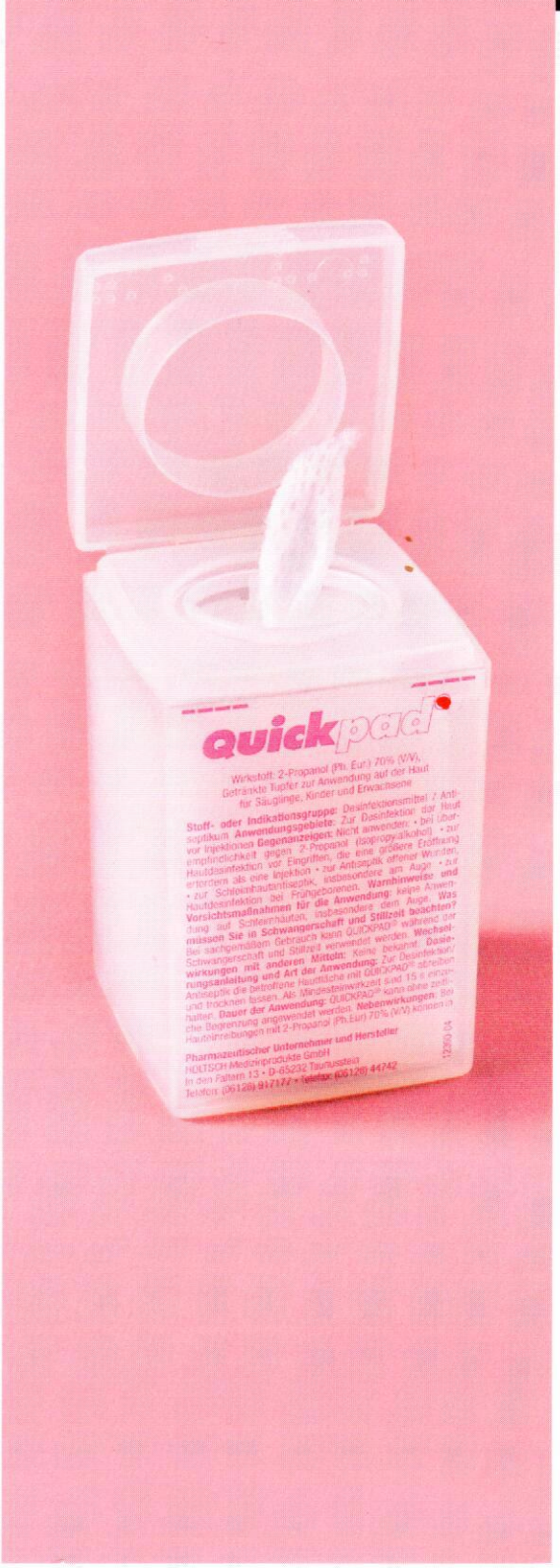
Quickpad

The Quickpad alcohol swab dispenser, being sterile and physiologically verified as harmless, is ideal for cleaning and disinfecting the skin.

The active agent 2 propanol acts as an effective, "mild on skin" disinfecting agent. The "swab tear-off" ready to use system allows for the single use of the swab. This makes Quickpad not only economical but also efficient in its use.

The lid of the Quickpad alcohol swab dispenser container seals air-tight, keeping the alcohol swabs moist and sterile. As a result, the swab dispenser has a particularly long shelf life of 24 months.

Quickpad is supplied ready for use and with its simple operation, can be used by specialists as well as patients for cleaning/ disinfecting the skin. An ideal product for diabetics and other users of self-injection syringes. Additionally, it is always possible through the transparent container to see the fill level and it is suitable for self-application by the patient.



Holtsch
Medizinprodukte GmbH
In den Faltern 13
D-65232 Taunusstein

T +49 6128 91717-7
F +49 6128 44742
M info@holtsch-med.com
W holtsch-med.com

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Quickpads

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

1.1. Product identifier

Quickpads

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

Disposable alcohol swabs for cleansing the skin

1.3. Details of the supplier of the safety data sheet

Company name:	Holtsch Medizinprodukte GmbH	
Street:	In den Faltern 13	
Place:	D-65232 Taunusstein	
Telephone:	+49(0)6128 917 177	Telefax: +49(0)6128 447 42
e-mail:	info@holtsch-med.com	
Contact person:	Malte Hertzberg	
Internet:	www.holtsch-med.com	
Responsible Department:	Responsible for the safety data sheet: sds@gbk-ingelheim.de	

1.4. Emergency telephone number:

+49 (0) 172 6123 572
In England and Wales: NHS 111 In Scotland: NHS 24 - dial 111

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:
Flammable liquid: Flam. Liq. 2
Serious eye damage/eye irritation: Eye Irrit. 2
Specific target organ toxicity - single exposure: STOT SE 3
Hazard Statements:
Highly flammable liquid and vapour.
Causes serious eye irritation.
May cause drowsiness or dizziness.

2.2. Label elements

Regulation (EC) No. 1272/2008

Signal word: Danger

Pictograms:

Hazard statements

H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.

Additional advice on labelling

According to the EC hazardous substance regulations in compliance with the EC cosmetic product regulations this product must not be labelled as a hazardous substance.

2.3. Other hazards

According to Regulation (EC) No 1907/2006 (REACH) none of the substances, contained in this product are a PBT / vPvB substance.
If swallowed in higher quantities risk of intestinal passage obstruction.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Disposable swab impregnated with 70%-Isopropanol (0,46 ml per swab).

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
67-63-0	Propan-2-ol			0,46 ml %
	200-661-7	603-117-00-0	01-2119457558-25	
	Flam. Liq. 2, Eye Irrit. 2, STOT SE 3; H225 H319 H336			

Full text of H and EUH statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

No specific precautions required.

After inhalation

Move to fresh air in case of accidental inhalation of vapours or decomposition products.
In the event of symptoms refer for medical treatment.

After contact with skin

No specific precautions required.

After contact with eyes

Rinse immediately with plenty of water, also under the eyelids.
If eye irritation persists, consult a specialist.

After ingestion

Consult a physician.

4.2. Most important symptoms and effects, both acute and delayed

Causes serious eye irritation.
May cause drowsiness or dizziness.
If swallowed in higher quantities risk of intestinal passage obstruction.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptoms.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Alcohol-resistant foam, dry chemical, carbon dioxide (CO2), water-spray.

Unsuitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

Fire may produce:
carbon monoxide and carbon dioxide

5.3. Advice for firefighters

Use breathing apparatus with independent air supply.
Protective suit.

Additional information

Vapours are heavier than air and spread along ground.
The vapour/air mixture is explosive, even in empty, uncleaned receptacles.
Cool containers at risk with water spray jet.
Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

In case of vapour formation use respirator.
Ensure adequate ventilation.
Use personal protective clothing.
Keep away sources of ignition.
Avoid contact with skin, eyes and clothing.

6.2. Environmental precautions

Do not discharge into the drains/surface waters/ground water.

6.3. Methods and material for containment and cleaning up

Take up mechanically and collect in suitable container for disposal.

6.4. Reference to other sections

Observe protective instructions (see Sections 7 and 8).
Information for disposal see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

When using do not eat, drink or smoke.
Avoid contact with eyes.

Advice on protection against fire and explosion

Keep away from heat and sources of ignition.
Don't smoke.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Protect against direct sun radiation.
Keep containers tightly closed in a cool, well-ventilated place.

Hints on joint storage

Incompatible with:
Oxidizing agents
Alkaline metals and earth alkaline metals.

Further information on storage conditions

Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

Disposable alcohol swabs for cleansing the skin

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
67-63-0	Propan-2-ol	400	999		TWA (8 h)	WEL
		500	1250		STEL (15 min)	WEL

8.2. Exposure controls

Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas.

Protective and hygiene measures

When using do not eat, drink or smoke.
Do not inhale vapours.
Avoid contact with eyes.

Eye/face protection

Not required under normal use.

Hand protection

Not required under normal use.

Skin protection

Not required under normal use.

Respiratory protection

No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Tissue, tinctured with clear disinfectant solution
Colour:	
Odour:	Alcoholic

		Test method
pH-Value:	n.d.	
Changes in the physical state		
Melting point:	n.d.	
Initial boiling point and boiling range:	n.d.	
Sublimation point:	n.a.	
Softening point:	n.d.	
Flash point:	12 °C	*)
Flammability		
Solid:	Combustible.	
Gas:	n.a.	

Explosive properties

The product is considered non-explosive; nevertheless explosive vapour/air mixture can be generated

Lower explosion limits:	2,0 vol. %	*)
Upper explosion limits:	12 vol. %	*)
Ignition temperature:	425 °C	*)
Auto-ignition temperature		
Solid:	The product is not self-igniting	
Gas:	n.a.	

Decomposition temperature:	n.d.

Oxidizing properties

Not oxidising.

Vapour pressure: (at 20 °C)	43 hPa *)
Density (at 20 °C):	0,87 g/cm³ *)
Bulk density:	n.d.
Water solubility: (at 20 °C)	Miscible *)

Solubility in other solvents

n.d.

Viscosity / dynamic:	n.a.
Viscosity / kinematic:	n.a.
Flow time:	n.a.
Vapour density:	n.d.
Evaporation rate:	n.d.
Solvent separation test:	n.d.
Solvent content:	n.d.

9.2. Other information

*) All data refer to the solution

SECTION 10: Stability and reactivity

10.1. Reactivity

No decomposition if stored and applied as directed.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No hazardous reactions known.

10.4. Conditions to avoid

Heating can release vapours which can be ignited.

10.5. Incompatible materials

Oxidizing agents
Alkaline metals and earth alkaline metals.

10.6. Hazardous decomposition products

No hazardous decomposition products known.
Fire may produce:
Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Based on available data, the classification criteria are not met.
Propan-2-ol
LD50/oral/rat: 5045 mg/kg [RTECS]
LD50/dermal/rabbit: 12800 mg/kg
LC50/inhalation/rat: 46,5 mg/l/4h [RTECS]

Irritation and corrosivity

Causes serious eye irritation.
Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

May cause drowsiness or dizziness.

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.

Additional information on tests

Classification in compliance with the assessment procedure specified in the Regulation (EC) no 1272/2008.

Practical experience

Other observations

If appropriately handled and if in accordance with the general hygienic rules, no damages to health have become known.
Sometimes short-term reddening of skin may occur.
May cause irritation of the mucous membranes.
If swallowed in higher quantities risk of intestinal passage obstruction.

SECTION 12: Ecological information

12.1. Toxicity

Propan-2-ol
LC50/Lepomis macrochirus/96 h = 1400 mg/l [ECOTOX DATABASE]
EC50/Daphnia magna/48 h = 13299 mg/l [IUCLID]
EC50/Desmodesmus subspicatus/72 h > 1000 mg/l [IUCLID]

12.2. Persistence and degradability

Propan-2-ol
Biodegradable (OECD): 95% [OECD 301 E]

12.3. Bioaccumulative potential

Propan-2-ol
Product has a low bioaccumulating potential. Log Pow: 0,05 [OECD 107]

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

According to Regulation (EC) No 1907/2006 (REACH) none of the substances, contained in this product are a PBT / vPvB substance.

12.6. Other adverse effects

Low hazard to waters.

Further information

Product is not allowed to be discharged into aquatic environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Can be incinerated, when in compliance with local regulations.

List of Wastes Code - residues/unused products

180106 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE); wastes from natal care, diagnosis, treatment or prevention of disease in humans; chemicals consisting of or containing hazardous substances; hazardous waste

Contaminated packaging

Empty containers should be taken for local recycling, recovery or waste disposal.
Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse.
Packaging that cannot be cleaned should be disposed of like the product.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number:	UN 3175
14.2. UN proper shipping name:	SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (Propan-2-ol)
14.3. Transport hazard class(es):	4.1
14.4. Packing group:	II
Hazard label:	4.1

Classification code:	F1
Limited quantity:	1 kg / 30 kg
Excepted quantity:	E2
Transport category:	2
Hazard No:	40
Tunnel restriction code:	E

Inland waterways transport (ADN)

14.1. UN number:	UN 3175
14.2. UN proper shipping name:	SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (Propan-2-ol)
14.3. Transport hazard class(es):	4.1
14.4. Packing group:	II
Hazard label:	4.1

Classification code:	F1
Limited quantity:	1 kg / 30 kg
Excepted quantity:	E2

Marine transport (IMDG)

14.1. UN number:	UN 3175
14.2. UN proper shipping name:	SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (Propan-2-ol)
14.3. Transport hazard class(es):	4.1
14.4. Packing group:	II
Hazard label:	4.1

Marine pollutant:	No
Limited quantity:	1 kg / 30 kg
Excepted quantity:	E2
EmS:	F-A, S-I

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number:	UN 3175
14.2. UN proper shipping name:	SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (Propan-2-ol)
14.3. Transport hazard class(es):	4.1
14.4. Packing group:	II
Hazard label:	4.1

Limited quantity Passenger:	5 kg
Passenger LQ:	Y441
Excepted quantity:	E2
IATA-packing instructions - Passenger:	445
IATA-max. quantity - Passenger:	15 kg
IATA-packing instructions - Cargo:	448
IATA-max. quantity - Cargo:	50 kg

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: no

14.6. Special precautions for user

Take the usual precautions when handling with chemicals.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

The transport takes place only in approved and appropriate packaging.

SECTION 15: Regulatory information

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

EU regulatory information

2004/42/EC (VOC):	0,46 ml
Information according to 2012/18/EU (SEVESO III):	P5c FLAMMABLE LIQUIDS

National regulatory information

Employment restrictions:	Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

SECTION 16: Other information

Abbreviations and acronyms

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route
RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses
ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intér
IMDG = International Maritime Code for Dangerous Goods
IATA/ICAO = International Air Transport Association / International Civil Aviation Organization
MARPOL = International Convention for the Prevention of Pollution from Ships
IBC-Code = International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
REACH = Registration, Evaluation, Authorization and Restriction of Chemicals
CAS = Chemical Abstract Service
EN = European norm
ISO = International Organization for Standardization
DIN = Deutsche Industrie Norm
PBT = Persistent Bioaccumulative and Toxic
vPvB = Very Persistent and very Bio-accumulative
LD = Lethal dose
LC = Lethal concentration
EC = Effect concentration
IC = Median immobilisation concentration or median inhibitory concentration

Relevant H and EUH statements (number and full text)

H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.

Further Information

Data of items 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities.
The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge.
The delivery specifications are contained in the corresponding product sheet.
This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.
(n.a. = not applicable; n.d. = not determined)

'The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)