VEC: Platnosť certifikátov

Pre: SUKL CZ
Šrobárova 48, 100 41 Praha 10

Podľa pôvodného znenia nariadení č. 2017/745 a 2017/746 certifikáty, ktoré boli vydané ešte podľa smerníc č. 90/385/EHS a 93/42/EHS, **mali zostať v platnosti najdlhšie do 26. mája 2024.**

Podľa Európskeho parlamentu a Rady (cit.): *„Vzhľadom na správy od zdravotníckych pracovníkov o bezprostrednom riziku nedostatku pomôcok* ***je nevyhnutné urýchlene predĺžiť platnosť certifikátov vydaných v súlade so smernicami 90/385/EHS a 93/42/EHS a predĺžiť prechodné obdobie, počas ktorého sa môžu pomôcky, ktoré sú v súlade s uvedenými smernicami, zákonne uvádzať na trh.*** *Predĺženie by malo byť dostatočne dlhé na to, aby sa notifikovaným osobám poskytol čas potrebný na vykonanie posúdení zhody, ktoré sa od nich požadujú. Cieľom predĺženia je zabezpečenie vysokej úrovne ochrany verejného zdravia vrátane bezpečnosti pacienta a zabránenie nedostatku zdravotníckych pomôcok potrebných na bezproblémové fungovanie služieb zdravotnej starostlivosti, a to bez znižovania súčasných požiadaviek v oblasti kvality alebo bezpečnosti."*

V súlade s vyššie uvedeným účelom sa na trh alebo do používania môžu uvádzať zdravotnícke pomôcky s certifikátom vydaným ešte podľa smerníc č. 90/385/EHS a 93/42/EHS, a to do:

- **31. decembra 2027** v prípade všetkých pomôcok triedy III a implantovateľných pomôcok triedy IIb s výnimkou šijacieho materiálu, skôb, zubných výplní, zubných podpier, zubných koruniek, skrutiek, klinov, platničiek, drôtov, kolíkov a čapov, spôn a prípojok a svoriek
- **31. decembra 2028** v prípade pomôcok triedy IIb okrem tých, na ktoré sa vzťahuje písmeno a) tohto odseku, v prípade pomôcok triedy IIa a v prípade pomôcok triedy I uvádzaných na trh v sterilnom stave alebo pomôcok s meracou funkciou.

Zdroj:

NARIADENIE EURÓPSKEHO PARLAMENTU A RADY (EÚ) 2023/607

z 15. marca 2023,

ktorým sa menia nariadenia (EÚ) 2017/745 a (EÚ) 2017/746, pokiaľ ide o prechodné ustanovenia pre určité zdravotnícke pomôcky a diagnostické zdravotnícke pomôcky *in vitro*

Článok 1

1.Článok 120 sa mení takto:

a) v odseku 2 sa druhý pododsek nahrádza takto:

„Certifikáty vydané notifikovanými osobami v súlade so smernicami 90/385/EHS a 93/42/EHS od 25. mája 2017, ktoré boli stále platné 26. mája 2021 a ktoré neboli neskôr stiahnuté, zostávajú naďalej v platnosti po skončení obdobia uvedeného na

certifikáte do dátumu stanoveného v odseku 3a tohto článku uplatniteľného pre príslušnú rizikovú triedu pomôcok. Certifikáty vydané notifikovanými osobami v súlade s uvedenými smernicami od 25. mája 2017, ktoré boli stále platné 26. mája 2021 a ktorých platnosť uplynula pred 20. marcom 2023 sa považujú za platné do dátumov stanovených v odseku 3a tohto článku len vtedy, ak je splnená jedna z týchto podmienok:

a) výrobca a notifikovaná osoba predo dňom uplynutia platnosti certifikátu uzavreli v súlade s oddielom 4.3 druhým pododsekom prílohy VII k tomuto nariadeniu písomnú dohodu o posudzovaní zhody v súvislosti s pomôckou, na ktorú sa vzťahuje certifikát, ktorého platnosť uplynula, alebo v súvislosti s pomôckou, ktorá má danú pomôcku nahradiť;

b) odsek 3 sa nahrádza takto:
3a. Pomôcky s certifikátom, ktorý bol vydaný v súlade so smernicou 90/385/EHS alebo smernicou 93/42/EHS a ktorý je platný na základe odseku 2 tohto článku, sa môžu uvádzať na trh alebo uvádzať do používania do týchto dátumov:

a) 31. decembra 2027 v prípade všetkých pomôcok triedy III a implantovateľných pomôcok triedy IIb s výnimkou šijacieho materiálu, skôb, zubných výplní, zubných podpier, zubných koruniek, skrutiek, klinov, platničiek, drôtov, kolíkov a čapov, spôn a prípojok a svoriek;

3c. Pomôcky uvedené v odsekoch 3a a 3b tohto článku sa môžu uvádzať na trh alebo uvádzať do používania do dátumov uvedených v daných odsekoch len vtedy, ak sú splnené tieto podmienky:

a) tieto pomôcky sú naďalej v súlade so smernicou 90/385/EHS alebo prípadne smernicou 93/42/EHS;

b) nevykonali sa žiadne podstatné zmeny konštrukčného návrhu a účelu určenia;

c) pomôcky nepredstavujú neprijateľné riziko pre zdravie alebo bezpečnosť pacientov, používateľov alebo iných osôb, alebo pre iné aspekty ochrany verejného zdravia;

d) výrobca najneskôr 26. mája 2024 zaviedol systém riadenia kvality v súlade s článkom 10 ods. 9;

e) výrobca alebo jeho splnomocnený zástupca najneskôr 26. mája 2024 podal notifikovanej osobe v súlade s oddielom 4.3 prvým pododsekom prílohy VII formálnu žiadosť o posúdenie zhody v súvislosti s pomôckou uvedenou v odseku 3a alebo 3b tohto článku alebo v súvislosti s pomôckou, ktorá má nahradiť danú pomôcku, pričom notifikovaná osoba a výrobca uzavreli najneskôr 26. septembra 2024 písomnú dohodu v súlade s oddielom 4.3 druhým pododsekom prílohy VII.

Záver:
Máme za to, že na základe NARIADENIE EURÓPSKEHO PARLAMENTU A RADY (EÚ) 2023/607, je predmetný certifikát (po doložení všetkých príslušných a vyžadovaných dokumentov) v platnosti do 31.12.2027.

V Trnave 2.6.2025

SOLAZO s.r.o.
Veterná 8760/42, 917 01 Trnava
IČO: 53274687, DIČ: 2121320300
IČ DPH: SK2121320300

Solazo s.r.o.
Mgr. Rastislav Sojka

Prílohy:

1. Certifikát : Hangzhou Singclean 12024-2018-CE-RGC-NA-PS Rev 3.0
2. Contract between Singclean and DNV for Medical Devices on MDR Page 1-4
3. Statement of meeting the extension conditions_sukl

DNV

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until
12024-2018-CE-RGC-NA-PS Rev 3.0	PRJC-230816-2010-PRC-CHN	18 January 2023

This is to certify that the quality system of:

Hangzhou Singclean Medical Products Co., Ltd.

No. 125(E), 10th Street, Hangzhou Economic and Technological Development Zone, Zhejiang, China

For design, production and final product inspection/testing of:

MEDICAL SODIUM HYALURONATE GEL

Has been assessed with respect to:

the conformity assessment procedure described in Annex II of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 10 March 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Mariann Jeremiassen
Principal assessor

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	19 January 2018
1.0	New brand name added (Quickclean, SingJoint)	30 October 2020
2.0	New brand name added (Singclean)	05 November 2020
3.0	**New brand name added (JOINT MD, Arthro One)**	**10 March 2021**

Products covered by this Certificate:

Product Description	Product Name	Class
Medical Sodium Hyaluronate Gel for Bone Joint (Brand: Quickclean, SingJoint)	10mg/ml: 1.0ml, 2.0ml, 2.5ml 12mg/ml: 1.0ml, 2.0ml, 2.5ml 20mg/ml: 2.0ml, 3.0ml	III*
Medical Sodium Hyaluronate Gel for Bone Joint (Brand: JOINT MD)	10mg/ml: 2.0ml	III*
Medical Sodium Hyaluronate Gel for Bone Joint (Brand: Arthro One)	20mg/ml: 2.0ml, 3.0ml	III*
Medical Sodium Hyaluronate Gel for Anti-adhesion (Brand: Singclean)	10mg/ml: 0.5 ml, 0.75ml, 1.0ml, 2.0 ml, 2.5 ml, 3.0ml, 5.0 ml, 15 ml, 17ml, 20 ml	III**

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 12027-2018-CE-RGC-NA-PS Rev 2.0

* * Design assessment is covered by a separate EC-Design Examination Certificate No.: 12028-2018-CE-RGC-NA-PS Rev 1.0

Sites covered by this certificate

Site Name	Address
Hangzhou Singclean Medical Products Co., Ltd.	No. 125(E), 10th Street, Hangzhou Economic and Technological Development Zone, Zhejiang, China

EU Representative

Hangzhou Singclean Medical Products Filial Sweden, Norra Rosenbergsgatan 2A 42676 VÄSTRA FRÖLUNDA, Sweden

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. The Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate

DNV

DNV Agreement

YOUR CONTRACT FOR Medical Devices Certification Services

医疗器械认证服务协议

Quotation No. / 报价单号: 284225

作为（公告机构）（认证组织），DNV Product Assurance 对所政治性的活动负有全部业务、财务和法律责任。在适用的情况下，DNV 市场部被授权代表公告机构（认证组织）与客户一起管理这些协议，包括支付和收取费用

No work will commence until one original or digital copy of this Agreement, duly signed and dated by the Customer, has been returned to the Notified Body (Auditing Organization) or DNV Market Unit, as applicable. The execution of the work will be planned between DNV (Market unit) and customer when the agreement has been signed.

在客户正式签署并注明日期的书面协议或电子协议副本，并返回公告机构（认证组织）或 DNV 市场部之前，不会开始任何相关工作。DNV（市场部）和客户之间规划的工作将在所有协议签署以后进行

The Agreement consists of this Form of Agreement including the sections: The Scope of Work, the Investment, the Additional Costs and Payment Conditions, and the General Terms & Conditions, together with any attachments incorporated herein, and the following appendices (when applicable):

本协议包括以下章节：工作范围、投入资金、额外费用和付款条件、一般条款和条件，以及本协议中包含的任何附件，以及以下附录文件（如适用）。

Specific requirements to Customer arising from the Notified Body's designation/notification, the regulation, accreditation and MDSAP are included in the Terms & Conditions in this Agreement including special terms for the Medical Devices Regulation and MDSAP. The Certification Process is available on the website. It may be updated following changes in the applicable framework or in the Notified Body (Auditing Organization) processes.

在本协议的条款和条例中包含公告机构的特别指定/通知、条例和 MDSAP 对客户提出的具体要求包括医疗器械法规和 MDSAP 的特殊条款。公告机构（认证组织）认证程序可在网站上查阅。适用的框架或公告机构（认证组织）流程发生变化后对其进行更新。

The Work is partially provided by DNV Market Unit. The Notified Body (Auditing Organization, Certification body), by its signature on this Agreement confirms its ultimate responsibility for the provision of the Work, and also hereby reserves the right to exercise the rights set out herein, including but not limited to, the right to issue, suspend, withdraw and renew certificates under this Agreement. All payments should be directed to DNV Market Unit.

这项工作部分由 DNV 市场部提供。公告机构（认证组织）在本协议上签字确认其对提供工作的最终责任，并在此保留行使本协议规定的权利，包括但不限于根据本协议签发、暂停、撤回和续签证书的权利。所有付款应直接支付给 DNV 市场部。

On behalf of Customer		**DNV Market Unit**		**DNV Product Assurance AS**	
Place: Hang Zhou 杭州	Date: 2021-09-02	Place: Beijing 北京	Date: 2021-08-31	Place: Oslo	Date: 2021-09-04
Signature Name: Qiangjia Function: *The undersigned hereby declares:* • *that the information given in this document is correct, and that the same application has not been lodged with any other Notified Body* • *The declarations and data in the Quotation Request form remain valid.*		Signature Name: Chen Xi Function: Customer Service Manager for MDD of PC. BAG Group. China/医疗器械产品认证客户服务经理，大中国区		Signature Bjørg Synnøve Nesgård Name: Bjørg Synnøve Nesgård Function: Operations Manager Medical	

Customer (Manufacturer) **客户（制造商）** **Special requirements apply when Authorized representative applies on behalf of customer** **当授权代表代表客户申请时，适用特殊要求**	Account Name: 客户名称： Hangzhou Singclean Medical Products Co., Ltd. 杭州协合医疗用品有限公司 VAT/Tax#: VAT/税号：91330101747181911R	Address: 地址： No. 125 (E), 10th Street, Hangzhou Qiantang New Area, Zhejiang, China 浙江省杭州市钱塘新区 10 号大街（东）125 号
	Contact Person:Kong Xiang Ping 联系人：孔祥萍	Tel: 电话：+86 (571) 63431868 E-mail: 电子邮件 kongxp@hzxhe.com
DNV	Legal Entity: 法人实体： DNV Business Assurance (China) Co., Ltd. 上海挪华威认证有限公司	Address: House 9, No. 1591 Hongqiao Road, Changning District, Shanghai, 200336, P. R. China 地址：上海市长宁区虹桥路 1591 号 9 号楼
	Contact person: CHEN XI 联系人 陈 曦	Tel / 电话：+86 10 6562 7682 E-mail / 电子邮件：xi.chen@dnvgl.com
Notified Body /Auditing organization/certification body	Legal Entity: 法人实体 **DNV Product Assurance AS**	Notified Body nr: **2460**

Section 1: Form of Agreement

This Product Certification Agreement (the Agreement) constitutes the entire agreement between the Parties for Notified Body services under the Medical Devices Regulation – 2017/745/EU and also serves as the application to Notified Body 2460 for services under this Regulation. This Product Certification Agreement (the Agreement) constitutes the entire agreement between the Parties for service under ISO 13485:2016. This Product Certification Agreement (the Agreement) constitutes the entire agreement between the Parties for Auditing Organization services under Medical Device Auditing Organization [MDSAP]. The agreement is based on the information provided by customer in the Quotation Request Form and customer hereby confirms that information provided is still correct and exhaustive. The Notified Body may cancel the contract in case there are significant changes to the information provided in the Quotation Request Form. Such changes, leading to a need for further activities, will potentially render section 3 "Investment Summary" invalid. Unless otherwise agreed with Customer, all changes to this information provided will automatically lead to a prolongation of any estimated, tentative, indicative or agreed time-schedule for the Work.

本产品认证协议（协议）构成双方根据医疗器械条例-2017/745/EU 的通知机构服务的整个协议，并作为根据本条例向通知机构 2460 提供服务的申请。 本产品认证协议（协议）构成双方在医疗器械审计组织[MDSAP]下的服务的整个协议]。 该协议是基于客户在报价申请表中提供的信息，客户特此确认所提供的信息仍然是正确和详尽的。 如果报价申请表中提供的信息有重大变化，通知机构可以取消合同。 这种变化导致需要开展进一步的活动，可能使第 3 节 "投资摘要" 无效。 除非与客户另有协议，对所提供的信息的所有更改将自动导致工作的任何估计、暂定、指示性或商定时间表的延长

The Agreement shall supersede and invalidate all prior representations relating to the subject matter hereof. Customer's terms and conditions included in any of Customer's Purchase Orders shall be null, void and disregarded. No other amendment and/or variation to the Agreement shall be valid unless duly signed by both parties with reference to the relevant parts of this Agreement.

本协议应取代失效的且与原协议标有关的所有陈述。 客户的条款和条件包括任何客户的订单应是无效的。 除非双方就本协议的相关部分签订正式协议，否则协议的任何其它修改和/或变更均为无效

DNV Product Assurance AS (The Notified Body, Certification body and Auditing Organization) has the full operational, financial and legal responsibility for the activities performed. When applicable, a DNV Market unit is authorized to administer this Agreement, including payments and collection of fees, with Customer on behalf of the Notified Body (Auditing Organization).

2. Scope of Work under MDR
MDR 的工作范围

Scope of Work and information is based on your Quotation Request form dated: 2021-06-02
认证范围和信息基于递交的报价申请表日期: 2021-06-02

Applicable scheme and Notified Body.	Notifying/Designating Authority.
Medical Devices Regulation – 2017/745/EU *Notified Body 2460 Norway, DNV Product Assurance AS*	The Norwegian Medicines Agency, Norway

a. Products to be certified （认证产品信息）

Product Name/Identifier	Classification	MDA/MDN,MDT and MDS codes	CMDN (Only IIb and higher)	Conformity Assessment Annexes used (Annex IX, Annex IX including section 4 or Annex XI part A)
Medical Sodium Hyaluronate Gel for Bone Joint	III	*MDN1102* *MDT2008, MDT2011* *MDS1005.3*		Annex IX

b. Sites covered （覆盖认证场地）

Site Name (if relevant)	Address
Hangzhou Singclean Medical Products Co., Ltd. 杭州协合医疗用品有限公司	No. 125 (E), 10th Street, Hangzhou Qiantang New Area, Zhejiang, China 浙江省杭州市钱塘新区 10 号大街（东）125 号

c. Critical subcontractor (Outsourced processes) or suppliers of Materials /components/services to be audited by the Notified Body
公告机构需审核的关键供应商（外包的流程）或 材料/部件/服务供应商

Company Name	Address

杭州协合医疗用品有限公司
Hangzhou Singclean Medical Products Co., Ltd.

质量第一，管理优先
建和谐企业，创协合品牌
Quality First, Management Priority,
Building Harmonious Enterprise, Creating Singclean Brand

Statement of meeting the extension conditions

To whom it may concern,

We hereby declare that:

(a) the Medical Sodium Hyaluronate Gel for Bone Joint QuickClean continues to comply with 93/42/EEC Medical Device Directive:

(b) there are no significant changes in the design and intended purpose;

(c) the device has no unacceptable risk for health and security of patients, users and other persons or unacceptable results against the protection of public health;

(d) We confirm that we already established a Quality Management System according to MDR Article 10(9).

Best Regards,

SIGN: 杭州协合医疗用品有限公司 HANGZHOU SINGCLEAN MEDICAL PRODUCTS CO.,LTD Date: 2023.06.29

General Manager: Weiqing Sun

Telephone No.: +86-571-63431868

STAMP: Hangzhou Singclean Medical Products Co., Ltd.