Präqualifizierungsbestätigung

Die QVH Service GmbH bestätigt hiermit, dass, gemäß dem § 126 Absatz 1a SGB V, die

Dr. Hönle Medizintechnik GmbH

Dornierstraße 4
82205 Gilching

IK: 590910502

die Voraussetzungen für eine ausreichende, zweckmäßige und funktionsgerechte Herstellung, Abgabe und Anpassung der Hilfsmittel gemäß § 126 Absatz 1 SGB V nachweislich für folgende Versorgungsbereiche erfüllt:

06A 09A

Fachliche Leitung: Prof. Dr. rer. Nat. Karl Hönle

Zertifikatsnummer: 201030/103

Gültig von: 12.08.2020

Gültig bis: 11.08.2025

DAkkS
Deutsche
Akkreditierungsstelle
D-ZE-20976-01-00

Berlin, 12. August 2020

QVH Service GmbH
Werderscher Markt 15, 10117 Berlin
Fon +49 (0)30 41 40 23-20, Fax -71
[illegible]-praequalifizierung.de

QVH Service GmbH

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

TÜV SÜD
Product Service

Certificate

No. Q5 023228 0012 Rev. 00

Holder of Certificate: **Dr. Hönle Medizintechnik GmbH**
Dornierstr. 4
82205 Gilching
GERMANY

Facility(ies): Dr. Hönle Medizintechnik GmbH
Thura Mark 8+10, 06780 Zörbig, GERMANY

Certification Mark:

Scope of Certificate: **Design & development, production, distribution and servicing of light therapy devices for the treatment of skin diseases as well as tap-water iontophoresis units including their accessories for the treatment of hyperhidrosis**

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). See also notes overleaf.

Report No.: 713135598

Valid from: 2018-12-20
Valid until: 2021-09-20

Date, 2018-12-20

Stefan Preiß

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

A4 / 07.17

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

TÜV®

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 023228 0013 Rev. 00

Manufacturer: **Dr. Hönle Medizintechnik GmbH**
Dornierstr. 4
82205 Gilching
GERMANY

Facility(ies): Dr. Hönle Medizintechnik GmbH
Thura Mark 8+10, 06780 Zörbig, GERMANY

Product Category(ies): **Light therapy devices and tap-water iontophoresis units including accessories for treatment of hyperhidrosis**

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.: 713136709

Valid from: 2019-01-31
Valid until: 2023-07-23

Date, 2019-01-31

Stefan Preiß

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

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

A4 / 07.17

NATIONAL INSTITUTE OF PUBLIC HEALTH
Šrobárova 49/48
Praha 10
100 00
Czech Republic

YOUR REFERENCE:	87/2021
DATE:	December 15, 2021
OUR REFERENCE:	**SZÚ/16141/2021; EX 220028 5-187-22**
	Kristina Kejlová, M.Sc., Ph.D.
PHONE/FAX:	+420 2 6708 2327
E-MAIL:	kristina.kejlova@szu.cz
Date:	February 17, 2022

Biomedica, spol. s r.o.
Pekařská 8
155 00 Praha 5

Subject: EXPERT OPINION on the assessment of the In Vitro Phototoxicity Test on Skin Model Epiderm.

SUBJECT OF APPLICATION:
Regarding your application of 15-December-2021 for evaluation of the In Vitro Phototoxicity Test on Skin Model Epiderm, we hereby report:

SUBMITTED SAMPLE:
TM1 – VITISTOP / VITIPRO

Sponsor:
Biomedica, spol. s r.o., Pekařská 8, 155 00 Praha 5 – Czech Republic

SUBMITTED DOCUMENTATION:
Not submitted.

PERFORMED TESTS:
The method is designed for biological testing of chemicals, consumer products, cosmetics, household products, etc., for their potential to elicit phototoxic effects on human skin. The in vitro test utilizing reconstructed human epidermis models was optimized and adapted on the basis of a validated in vitro phototoxicity method for chemicals (OECD TG 498: In vitro Phototoxicity - Reconstructed Human Epidermis Phototoxicity test method). The procedure is based on SOP supplied by the model manufacturer MatTek, which is included in each shipment of the tissues and is included in the primary documentation of the study.

EXPERT OPINION:
The test was performed by the Centre for Laboratory Testing, accredited by the Czech Accreditation Institute (Accredited Laboratory No.1206), Centre of Toxicology and Health Safety.

CONCLUSION:
The test material **VITISTOP / VITIPRO** has no phototoxic potential under the test conditions of the Human Epidermis Phototoxicity Test using the skin model EpiDerm.

National Institute of Public Health
Centre of Toxicology and Health Safety
Šrobárova 49/48, 100 00 Praha 10
Czech Republic

Dagmar Jírová, M.D., Ph.D.
Head of
Centre of Toxicology and Health Safety

Centre of Toxicology and Health Safety

National Institute of Public Health
Šrobárova 49/48
100 00 Prague 10
Czech Republic

FINAL REPORT
IN VITRO PHOTOTOXICITY TEST ON SKIN MODEL EPIDERM

Study Title: In vitro Phototoxicity: Reconstructed Human Epidermis Phototoxicity test method

Study No.: SZÚ/16141/2021; 5-187-22

Test material:

TM1 - VITISTOP / VITIPRO

Sponsor: Biomedica, spol.s r.o.

Address: Pekařská 8, 155 00 Praha 5, Czech Republic

Kristina Kejlová, M.Sc., Ph.D. **Signature:**.....**Date:** 14.2.2022
Study Director

Marian Rucki, M.Sc., Ph.D. **Signature:**.....**Date:** 14.2.2022
Test Facility Director

Experimental starting date: 8.2.2022

Experimental completion date: 11.2.2022

Final Study completion date: 14.2.2022

National Institute of Public Health
Centre of Toxicology and Health Safety
Šrobárova 49/48, 100 00 Praha 10
Czech Republic