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

Herstellung und Vertrieb von
Arzneimitteln, Medizinprodukten,
Sonderanfertigungen und Promotion

In den Faltern 13 - 65232 Taunusstein

Telefon +49 (6128) 91717-7
Telefax +49 (6128) 91717-9
Telefax +49 (6128) 4 47 42
e-mail: info@holtsch-med.com

Ust.-Ident.Nr. (VAT) DE811962816

Declaration of Conformity

Product category: Pre-injection cleansing swab

Product (Name, Type)	Size	Reference
Swab dispenser Quickpad saturated with Isopropyl alcohol, sterilized	150 pads	N10000K

We herewith declare under our sole responsibility that the above mentioned product meet all the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices as amended by Directive 2007/47/EC, which apply to it, as stated in Annex VII.

i. V.

Dr. Michael Gluschke
Head of Regulatory Affairs