

Porta-Objetos
Cubre-Objetos

Lames
Lamelles

Microscope Slides
Cover Slips

Objektträger
Deckgläser



1.1.18 **"Technical File"** means the file relation to the Product which contains the information concerning the Product required by the IVD Directive. Part A of the Technical File contains the following information only:

a) Name of Product or Product family

Microscope slides and coverglass

b) Description of Products, including variants

Various types of microscope slides and coverglass; please see our pricelist for details.

c) A statement of the intended use

Microscope slides are for microscopical examinations deriving from samples of the human body, to produce slide preparations and for their archivation.

Coverglass are for covering slide preparations and to archive them, deriving from samples of the human body.

d) Product classification and conformity assessment route

The nomenclature term is "DATA MANAGEMENT SOFTWARE/CONSUMABLES" and the nomenclature code 27-02 by using the EDMS-classification.

The classification is "Other devices (all devices except Annex II of the Directive 98/79/EC and self-testing devices)".

The Waldemar Knittel Glasbearbeitungs GmbH has implemented and operates a quality management system in compliance with the requirements of the quality standard ISO 9001:2008 and ISO 13485:2003. The Certificates are valid until July 31st 2017.

e) Name and address of the Supplier and a named contact

Waldemar Knittel Glasbearbeitungs GmbH

Varrentrappstraße 5, D-38114 Braunschweig, Germany

Tel: ++49 (0)531 - 59000 - 0

Fax: ++49 (0)531 - 59000 - 36

Safety officer for medical devices pursuant to § 30 (2) Medical Device Act, MPG:

Mr. Waldemar Knittel, e-mail: fabio.Insalata@Knittel-Glaeser.de

f) This Agreement as may be amended from time to time by agreement in writing of the Parties

g) Details of the Manufacturer's and Supplier's Notified Body where appropriate

Bezirksregierung Braunschweig

Bohlweg 38, D-38100 Braunschweig, Germany

Tel: ++49 (0)531 - 4840

Fax: ++49 (0)531 - 4843616

E-mail: mpg@br-bs.niedersachsen.de

registered under code: "DE/CA08"

Manufacturer code : DE/0000041767

h) A list of applicable standards

ISO 8037/1:1986 "Optics and optical instruments - Microscope slides - Part 1: Dimensions, optical properties and marking"

ISO 8255/1:1986 "Optics and optical instruments - Microscope coverglass - Part 1: Dimensional tolerances, thickness and optical properties"

ISO 9001:2008 Certificate issued KIWA international Cert. GmbH
Schlossmühlendamm 30, 21073 Hamburg, Germany on
August 11th 2011, valid until July 31st 2014
"Manufacturing and distribution of microscope slides and coverslips for microcopy and analytic research"

i) A "Declaration of Conformity"

Please see attachment

last updated: Jan 7th 2015

Waldemar Knittel Glasbearbeitungs GmbH

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V.A.T. Reg. Nr.: DE 114883519
Steuer-Nr.: 14/202/45519

Geschäftsführer:
Waldemar Knittel

Sitz Braunschweig
Handelsreg. Amtsgericht
Braunschweig, HRB 2471

Commerzbank

BLZ 270 400 80, Konto 530 395 300
IBAN DE11 2704 0080 0530 3953 00
SWIFT-BIC COBA DE FF
Nord/LB Braunschweig
BLZ 250 500 00, Konto 1 548 700
IBAN DE 70 2505 0000 0001 5487 00
SWIFT-BIC NOLA DE 2H

Dresdner Bank

BLZ 270 800 60, Konto 104 020 000
IBAN DE41 2708 0060 0104 0200 00
SWIFT-BIC DRES DE FF
Postbank Hannover
BLZ 250 100 30, Konto 5589 30-309
IBAN DE 37 2501 0030 0558 9303 09
SWIFT-BIC PBNK DE FF