

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 31<sup>st</sup> 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](mailto: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](mailto: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 31<sup>st</sup> 2014  
"Manufacturing and distribution of microscope slides and coverslips for microscopy and analytic research"

**i) A "Declaration of Conformity"**

Please see attachment

last updated: Jan 7<sup>th</sup> 2015

**Waldemar Knittel Glasbearbeitungs GmbH**

Varrentrappstraße 5  
D-38114 Braunschweig  
Telefon ++49 (0)531 / 59000-0  
Telefax ++49 (0)531 / 59000-36  
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