



Marienfeld * Am Wöllerspfad 4 * 97922 Lauda-Königshofen * Germany

EC Declaration of Conformity

In accordance with the requirements of Directive 98/79/EC for in vitro diagnostic medical devices, Annex I, we declare under our sole responsibility the conformity of the products.

We, the Paul Marienfeld GmbH & Co. KG, are registered as manufacturer respectively marketing authorisation holder of in-vitro diagnostic devices at DIMDI (Deutsches Institut für Medizinische Dokumentation und Information).

We hereby certify that the following in-vitro diagnostic devices comply with the essential requirements of Annex I to the Directive 98/79/EC and are suitable for use in accordance with these regulations.

Product specification	Registration no.
Cover glasses for blood and tissue sections	DE/CA 37/IVD/8/12

This registration number covers the products with the following Art.No.

0100032	0101040	0101173	0102062	0103222	0111600	0112640	0895222
0100042	0101050	0101182	0102112	0103242	0111620	0112650	0895242
0100052	0101052	0101192	0102122	0107032	0111640	0112700	
0100062	0101053	0101193	0102142	0107052	0111650	0117500	
0100112	0101060	0101202	0102152	0107172	0111700	0117520	
0100122	0101062	0101212	0102172	0107222	0112450	0117530	
0100142	0101092	0101222	0102192	0107242	0112500	0117550	
0100172	0101102	0101224	0102222	0111450	0112520	0117580	
0100192	0101112	0101232	0102242	0111500	0112530	0117640	
0100222	0101122	0101242	0103032	0111520	0112540	0117650	
0100242	0101123	0101244	0103042	0111530	0112550	0117700	
0101000	0101142	0101290	0103052	0111540	0112560	0895002	
0101010	0101143	0102032	0103062	0111550	0112580	0895012	
0101020	0101152	0102042	0103172	0111560	0112600	0895022	
0101030	0101172	0102052	0103192	0111580	0112620	0895202	

The conformity assessment procedure has been carried out in accordance with Annex III without point 6 of Directive 98/78/EC.

The above mentioned in-vitro diagnostic devices are neither covered by Annex II nor intended for self-application.

This declaration is valid until 25th May 2022.

Best regards,

Harry Marienfeld
Managing Director
Lauda-Königshofen, 24th October 2019



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We hereby certify that the following in-vitro diagnostic devices comply with the essential requirements of Annex I to the Directive 98/79/EC and are suitable for use in accordance with these regulations.

Product specification	Registration no.
Micro slides for blood smears	DE/CA 37/IVD/8/1

This registration number covers the products with following Art.No.

0703006	0703506	0704402	0705302	1000412	1100020
0703010	0703510	0704407	0705307	1000414	1100220
0703106	0704002	0704502	0705402	1000612	1100420
0703110	0704007	0704507	0705407	1000614	1100620
0703206	0704102	0705002	0705502	1000812	
0703210	0704107	0705007	0705507	1000912	
0703306	0704202	0705102	1000000	1005000	
0703310	0704207	0705107	1000004	1005200	
0703406	0704302	0705202	1000200	1005412	
0703410	0704307	0705207	1000204	1005612	

The conformity assessment procedure has been carried out in accordance with Annex III without point 6 of Directive 98/78/EC.

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Best regards,

Harry Marienfeld
Managing Director
Lauda-Königshofen, 24th October 2019

CERTIFICATE



MARIENFELD

ISO 9001:2015

DEKRA Certification GmbH hereby certifies that the organization

Paul Mariefeld GmbH & Co. KG

Scope of certification:

Development and production of laboratory glassware, slides and coverglasses for microscopy and distribution of products for laboratories

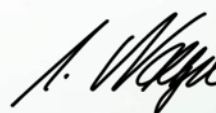
Certified location:

Am Wöllerspfad 4, 97922 Lauda-Königshofen, Deutschland

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. A14041218/2020.

Certificate registration no.:	31298871/8	Certificate valid from:	2020-08-25
Validity of previous certificate:	2020-08-24	Certificate valid to:	2023-08-24

Language translation


Dr. Gerhard Nagel
DEKRA Certification GmbH, Stuttgart, 2020-08-20



Deutsche
Akkreditierungsstelle
D-ZM-16029-01-01