

Declaration of Conformity



We

Aesku.Diagnostics GmbH & Co. KG

Mikroforum Ring 2, 55234 Wendelsheim, Deutschland / Germany

declare on our own responsibility that
the in-vitro diagnostic medical products from

Aesku.Diagnostics

listed in the annex
meet all the provisions of the Directive 98/79/EEC which apply to it.

Applied Standards:

DIN EN ISO 13485 (Certificate Number: MD 619745)

DIN EN 13612	DIN EN ISO 17050	DIN EN 23640	EN ISO 18113-1
DIN EN 13641	DIN EN ISO 17511	EN ISO 7010	EN ISO 18113-2
DIN EN ISO 14971	DIN EN 62366-1	EN 62304	EN ISO 18113-3
DIN EN ISO 15223-1	DIN EN ISO 19011	EN 61010-1	EN ISO 23640
			EN 61010-2-101

Conformity assessment procedure according to

Annex III
of Directive 98/79/EEC

The in-vitro diagnostics medical products of Aesku.Diagnostics are classified as

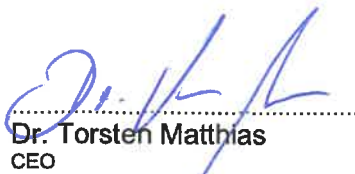
„other products“

according to the directive 98/79/EEC

This declaration of conformity loses its validity, if changes are made without
approval of the manufacturer.

Wendelsheim, 2021-12-01

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Ort, Datum / place, date


Dr. Torsten Matthias
CEO

Aesku.Diagnostics GmbH & Co. KG



Annex to the Declaration of Conformity dated 2021-06-28

for

Aesku.Diagnostics

The above-mentioned declaration of conformity issued by Aesku.Diagnostics GmbH & Co. KG covers products with the following REFs:

Product	Test	REF	EDMA	Registration Code
AESKULISA®				
AESKULISA® ANA-8S	ELISA 96 Tests	3100	12-10-01-01-00	DE/CA33/9001/001
AESKULISA® ANA-8Pro	ELISA 96 Tests	3101	12-10-01-01-00	DE/CA33/9001/002/1
AESKULISA® ENA-6S	ELISA 96 Tests	3102	12-10-01-02-00	DE/CA33/9001/003
AESKULISA® ENA-6Pro	ELISA 96 Tests	3103	12-10-01-90-00	DE/CA33/9001/004
AESKULISA® U1-70	ELISA 96 Tests	3104	12-10-01-14-00	DE/CA33/9001/005
AESKULISA® snRNP-C	ELISA 96 Tests	3105	12-10-01-14-00	DE/CA33/9001/006
AESKULISA® Sm	ELISA 96 Tests	3106	12-10-01-11-00	DE/CA33/9001/007
AESKULISA® SS-A	ELISA 96 Tests	3107	12-10-01-12-00	DE/CA33/9001/008
AESKULISA® SS-A-60	ELISA 96 Tests	3108	12-10-01-12-00	DE/CA33/9001/009
AESKULISA® SS-A-52	ELISA 96 Tests	3109	12-10-01-12-00	DE/CA33/9001/010
AESKULISA® SS-B	ELISA 96 Tests	3110	12-10-01-13-00	DE/CA33/9001/011
AESKULISA® Scl-70	ELISA 96 Tests	3111	12-10-01-10-00	DE/CA33/9001/012
AESKULISA® Ccnp-B	ELISA 96 Tests	3112	12-10-01-15-00	DE/CA33/9001/013
AESKULISA® Jo-1	ELISA 96 Tests	3113	12-10-01-08-00	DE/CA33/9001/014
AESKULISA® Rib-P	ELISA 96 Tests	3114	12-10-90-20-00	DE/CA33/9001/015
AESKULISA® ANA HEp-2	ELISA 96 Tests	3115	12-10-01-01-00	DE/CA33/9001/026/1
AESKULISA® DANA-Pro	ELISA 96 Tests	3116	12-10-01-01-00	DE/CA33/9001/088
AESKULISA® PM-Scl	ELISA 96 Tests	3117	12-10-01-09-00	DE/CA33/9001/099
AESKULISA® ANA Hep-2 quantitative	ELISA 96 Tests	3119	12-10-01-01-00	DE/CA33/AES/2008/1
AESKULISA® Sclero-Pro	ELISA 96 Tests	3121	12-10-01-90-00	DE/CA33/9001/016
AESKULISA® Nucleo-h	ELISA 96 Tests	3130	12-10-90-18-00	DE/CA33/9001/017
AESKULISA® dsDNA-Check	ELISA 96 Tests	3140	12-10-01-05-00	DE/CA33/9001/018
AESKULISA® dsDNA-A	ELISA 96 Tests	3141	12-10-01-05-00	DE/CA33/9001/019
AESKULISA® dsDNA-G	ELISA 96 Tests	3142	12-10-01-05-00	DE/CA33/9001/020
AESKULISA® dsDNA-M	ELISA 96 Tests	3143	12-10-01-05-00	DE/CA33/9001/021
AESKULISA® ssDNA-Check	ELISA 96 Tests	3144	12-10-01-06-00	DE/CA33/9001/022



Product	Test	REF	EDMA	Registration Code
AESKULISA® ssDNA-A	ELISA 96 Tests	3145	12-10-01-06-00	DE/CA33/9001/023
AESKULISA® ssDNA-G	ELISA 96 Tests	3146	12-10-01-06-00	DE/CA33/9001/024
AESKULISA® ssDNA-M	ELISA 96 Tests	3147	12-10-01-06-00	DE/CA33/9001/025
AESKULISA® Histone-C	ELISA 96 Tests	3150	12-10-01-07-00	DE/CA33/9001/027
AESKULISA® Histone-H1	ELISA 96 Tests	3151	12-10-01-07-00	DE/CA33/9001/028
AESKULISA® Histone-H2A	ELISA 96 Tests	3152	12-10-01-07-00	DE/CA33/9001/029
AESKULISA® Histone-H2B	ELISA 96 Tests	3153	12-10-01-07-00	DE/CA33/9001/030
AESKULISA® Histone-H3	ELISA 96 Tests	3154	12-10-01-07-00	DE/CA33/9001/031
AESKULISA® Histone-H4	ELISA 96 Tests	3155	12-10-01-07-00	DE/CA33/9001/032
AESKULISA® Rf-Check	ELISA 96 Tests	3160	12-11-01-10-00	DE/CA33/9001/033
AESKULISA® Rf-AGM	ELISA 96 Tests	3161	12-11-01-10-00	DE/CA33/9001/034
AESKULISA® alpha-Fodrin-A	ELISA 96 Tests	3162	12-10-90-90-00	DE/CA33/9001/035
AESKULISA® alpha-Fodrin-G	ELISA 96 Tests	3163	12-10-90-90-00	DE/CA33/9001/036
AESKULISA® alpha-Fodrin-Check	ELISA 96 Tests	3164	12-10-90-90-00	DE/CA33/9001/091
AESKULISA® RAV/CP-Detect	ELISA 96 Tests	3165	12-11-01-10-00	DE/CA33/9001/098/2
AESKULISA® CCP	ELISA 96 Tests	3166	12-11-01-90-00	DE/CA33/AES/2007/7
AESKULISA® MMP-3	ELISA 96 Tests	3168	12-11-01-90-00	DE/CA33/AES/2010/10/2
AESKULISA® MMP-3	ELISA 96 Tests	3171	12-11-01-90-00	DE/CA33/AES/2016/1
AESKULISA® SpA Detect	ELISA 96 Tests	3190	12-11-01-90-00	DE/CA33/AES/2016/6/1
AESKULISA® Cardioliipin-Check	ELISA 96 Tests	3202	12-10-90-01-00	DE/CA33/9001/049
AESKULISA® Cardioliipin-A	ELISA 96 Tests	3203	12-10-90-01-00	DE/CA33/9001/050
AESKULISA® Cardioliipin-GM	ELISA 96 Tests	3204	12-10-90-01-00	DE/CA33/9001/051
AESKULISA® β2-Glyco-A	ELISA 96 Tests	3205	12-10-90-04-00	DE/CA33/9001/053
AESKULISA® β2-Glyco-GM	ELISA 96 Tests	3206	12-10-90-04-00	DE/CA33/9001/054
AESKULISA® Serine-GM	ELISA 96 Tests	3207	12-10-90-03-00	DE/CA33/9001/055
AESKULISA® Inositol-GM	ELISA 96 Tests	3208	13-02-06-01-00	DE/CA33/9001/056/1
AESKULISA® Ethanolamine-GM	ELISA 96 Tests	3209	13-02-06-01-00	DE/CA33/9001/083
AESKULISA® Prothrombin-A	ELISA 96 Tests	3210	12-10	DE/CA33/9001/038
AESKULISA® Prothrombin-Check	ELISA 96 Tests	3211	13-02-06-01-00	DE/CA33/9001/103/1
AESKULISA® Choline-GM	ELISA 96 Tests	3212	13-02-06-01-00	DE/CA33/9001/102/1
AESKULISA® Thrombin-A	ELISA 96 Tests	3213	12-10-90-90-00	DE/CA33/9001/041/1
AESKULISA® Sphingomyelin-GM	ELISA 96 Tests	3214	13-02-06-01-00	DE/CA33/9001/100/1
AESKULISA® β2-Glyco-Check	ELISA 96 Tests	3215	12-10-90-04-00	DE/CA33/9001/089
AESKULISA® Phospholipid-Screen	ELISA 96 Tests	3216	13-02-06-01-00	DE/CA33/9001/081/1
AESKULISA® Phospholipid-Screen-A	ELISA 96 Tests	3219	13-02-06-01-00	DE/CA33/9001/045/1
AESKULISA® Phospholipid-8Pro-A	ELISA 96 Tests	3222	13-02-06-01-00	DE/CA33/9001/048/1
AESKULISA® Serine-Prothrombin-Check	ELISA 96 Tests	3223	13-02-06-01-00	DE/CA33/9001/090/1

Product	Test	REF	EDMA	Registration Code
AESKULISA® Phospholipid-Screen-GM	ELISA 96 Tests	3224	13-02-06-01-00	DE/CA33/9001/082/1
AESKULISA® Thrombin-Check	ELISA 96 Tests	3225	12-10-90-90-00	DE/CA33/9001/080/1
AESKULISA® Serine-Prothrombin-GM	ELISA 96 Tests	3226	13-02-06-01-00	DE/CA33/9001/090/1
AESKULISA® Serine-Prothrombin-A	ELISA 96 Tests	3227	13-02-06-01-00	DE/CA33/9001/090/1
AESKULISA® Thrombin-GM	ELISA 96 Tests	3228	12-10-90-90-00	DE/CA33/9001/086/1
AESKULISA® Prothrombin-GM	ELISA 96 Tests	3229	12-10-90-90-00	DE/CA33/9001/092/1
AESKULISA® Thrombo-Profile	ELISA 96 Tests	3230	13-02-06-01-00	DE/CA33/9001/085/1
AESKULISA® Phosphatidic acid-GM	ELISA 96 Tests	3231	13-02-06-01-00	DE/CA33/9001/084/2
AESKULISA® Phospholipid-8Pro-GM	ELISA 96 Tests	3232	13-02-06-01-00	DE/CA33/9001/087/1
AESKULISA® APS-Profile-GM	ELISA 96 Tests	3234	13-02-06-01-00	DE/CA33/9001/110/1
AESKULISA® Laminin	ELISA 96 Tests	3235	12-10-90-90-00	DE/CA33/9001/112
AESKULISA® Ethanolamine-A	ELISA 96 Tests	3236	13-02-06-01-00	DE/CA33/AES/9001/116/1
AESKULISA® Annexin V-GM	ELISA 96 Tests	3240	12-10-90-90-00	DE/CA33/9001/097
AESKULISA® Cardiolipin-GM	ELISA 96 Tests	3244	12-10-90-01-00	DE/CA33/9001/052
AESKULISA® Glycerol-A	ELISA 96 Tests	3254	13-02-06-01-00	DE/CA33/AES/2007/2
AESKULISA® Glycerol-GM	ELISA 96 Tests	3255	13-02-06-01-00	DE/CA33/AES/2007/2
AESKULISA® HIT II	ELISA 96 Tests	3290	13-02-06-90-00	DE/CA33/AES/2007/5/1
AESKULISA® HIT II Check	ELISA 96 Tests	3291	13-02-06-90-00	DE/CA33/AES/2007/5/1
AESKULISA® ANCA-Pro	ELISA 96 Tests	3301	12-10-01-03-00	DE/CA33/9001/101/1
AESKULISA® PR3 sensitive	ELISA 96 Tests	3302	12-10-90-10-00	DE/CA33/9001/057
AESKULISA® MPO	ELISA 96 Tests	3303	12-10-90-09-00	DE/CA33/9001/058
AESKULISA® BPI	ELISA 96 Tests	3304	12-10-01-03-00	DE/CA33/9001/101/1
AESKULISA® Elastase	ELISA 96 Tests	3305	12-10-01-03-00	DE/CA33/9001/060/1
AESKULISA® Cathepsin G	ELISA 96 Tests	3306	12-10-01-03-00	DE/CA33/9001/061/1
AESKULISA® Lactoferrin	ELISA 96 Tests	3307	12-10-01-03-00	DE/CA33/9001/101/1
AESKULISA® Lysozyme	ELISA 96 Tests	3308	12-10-01-03-00	DE/CA33/9001/101/1
AESKULISA® GBM	ELISA 96 Tests	3309	12-10-90-15-00	DE/CA33/9001/062
AESKULISA® Vasculitis-Screen	ELISA 96 Tests	3323	12-10-01-03-00	DE/CA33/9001/063/1
AESKULISA® a-Tg	ELISA 96 Tests	3400	12-04-01-08-00	DE/CA33/9001/064
AESKULISA® a-TPO	ELISA 96 Tests	3401	12-10-03-01-00	DE/CA33/9001/065
AESKULISA® Tg	ELISA 96 Tests	3402	12-10-03-04-00	DE/CA33/9001/066
AESKULISA® Gliadin-Check	ELISA 96 Tests	3500	12-10-90-06-00	DE/CA33/AES/9001/115
AESKULISA® GliA-A	ELISA 96 Tests	3501	12-10-90-06-00	DE/CA33/9001/067
AESKULISA® GliA-G	ELISA 96 Tests	3502	12-10-90-06-00	DE/CA33/9001/068
AESKULISA® tTg-A New Generation	ELISA 96 Tests	3503	12-10-90-22-00	DE/CA33/9001/069/1
AESKULISA® tTg-G New Generation	ELISA 96 Tests	3504	12-10-90-22-00	DE/CA33/9001/070/1
AESKULISA® ASCA-A	ELISA 96 Tests	3507	12-10-90-19-00	DE/CA33/9001/072

Product	Test	REF	EDMA	Registration Code
AESKULISA® ASCA-G	ELISA 96 Tests	3508	12-10-90-19-00	DE/CA33/9001/073
AESKULISA® Crohn's-Check	ELISA 96 Tests	3509	12-10-90-19-00	DE/CA33/9001/074/1
AESKULISA® CeliCheck New Generation	ELISA 96 Tests	3510	12-10-90-22-00	DE/CA33/9001/071/1
AESKULISA® Parietal Cell	ELISA 96 Tests	3511	12-10-90-11-00	DE/CA33/9001/113
AESKULISA® Intrinsic Factor	ELISA 96 Tests	3512	12-10-90-11-00	DE/CA33/AES/9001/114/1
AESKULISA® DGP-A	ELISA 96 Tests	3513	12-10-90-06-00	DE/CA33/AES/2010/1
AESKULISA® DGP-G	ELISA 96 Tests	3514	12-10-90-06-00	DE/CA33/AES/2010/1
AESKULISA® DGP-Check	ELISA 96 Tests	3515	12-10-90-06-00	DE/CA33/AES/2010/8
AESKULISA® iTg-GA New Generation	ELISA 96 Tests	3516	12-10-90-22-00	DE/CA33/AES/2010/15
AESKULISA® DGP-GA	ELISA 96 Tests	3517	12-10-90-06-00	DE/CA33/AES/2010/14
AESKULISA® mTg neo-epitope Check	ELISA 96 Tests	3520	12-10-90-90-00	DE/CA33/AES/2019/28
AESKULISA® Insulin	ELISA 96 Tests	3601	12-06-01-04-00	DE/CA33/9001/078/1
AESKULISA® LC-1	ELISA 96 Tests	3702	12-10-90-17-00	DE/CA33/9001/075/1
AESKULISA® LKM-1	ELISA 96 Tests	3703	12-10-90-08-00	DE/CA33/9001/076
AESKULISA® SLALP	ELISA 96 Tests	3704	12-10-90-17-00	DE/CA33/9001/079
AESKULISA® AMA-M2-G	ELISA 96 Tests	3705	12-10-90-02-00	DE/CA33/9001/077
AESKULISA® AMA-M2-M	ELISA 96 Tests	3706	12-10-90-02-00	DE/CA33/9001/111
AESKULISA® AMA-M2-Check	ELISA 96 Tests	3707	12-10-90-02-00	DE/CA33/9001/111
AESKULISA® β-2 Microglobulin	ELISA 96 Tests	3801	12-03-90-02-00	DE/CA33/9001/096
AESKULISA® Borrelia-G	ELISA 96 Tests	3802	15-01-06-05-00	DE/CA33/AES/2006/16
AESKULISA® Borrelia-M	ELISA 96 Tests	3803	15-01-06-06-00	DE/CA33/AES/2006/17
AESKULISA® 25OH Vitamin D	ELISA 96 Tests	3810	12-06-03-10-00	DE/CA33/AES/2013/1/1
AESKULISA® Protein C	ELISA 96 Tests	3901	13-02-06-08-00	DE/CA33/AES-2007/4
AESKULISA® Protein S	ELISA 96 Tests	3902	13-02-06-09-00	DE/CA33/AES/2007/3
AESKULISA® Free Protein S	ELISA 96 Tests	3903	13-02-06-09-00	DE/CA33/AES/2008/2
AESKULISA® Herpes Simplex Virus 1/2 IgG	ELISA 96 Tests	6042	15-04-03-05-00	DE/CA33/AES/2019/2
AESKULISA® Herpes Simplex Virus 1/2 IgM	ELISA 96 Tests	6043	15-04-03-06-00	DE/CA33/AES/2019/29
AESKULISA® Herpes Simplex Virus 1 (gG1) IgG	ELISA 96 Tests	6045	15-04-03-08-00	DE/CA33/AES/2019/3
AESKULISA® Herpes Simplex Virus 2 (gG2) IgG	ELISA 96 Tests	6048	15-04-03-11-00	DE/CA33/AES/2019/4
AESKULISA® Varicella Zoster Virus IgA	ELISA 96 Tests	6051	15-04-80-10-00	DE/CA33/AES/2019/17
AESKULISA® Varicella Zoster Virus IgG	ELISA 96 Tests	6052	15-04-80-10-00	DE/CA33/AES/2019/16
AESKULISA® Varicella Zoster Virus IgM	ELISA 96 Tests	6053	15-04-80-10-00	DE/CA33/AES/2019/15
AESKULISA® Parvovirus B19 IgG	ELISA 96 Tests	6062	15-04-80-09-00	DE/CA33/AES/2018/1
AESKULISA® Parvovirus B19 IgM	ELISA 96 Tests	6063	15-04-80-09-00	DE/CA33/AES/2018/2
AESKULISA® Measles Virus IgG	ELISA 96 Tests	6072	15-04-80-07-00	DE/CA33/AES/2019/30
AESKULISA® Measles Virus IgM	ELISA 96 Tests	6073	15-04-80-07-00	DE/CA33/AES/2019/31
AESKULISA® Clostridium tetani IgG	ELISA 96 Tests	6102	15-01-90-09-00	DE/CA33/AES/2021/1

Product	Test	REF	EDMA	Registration Code
AESKULISA® SARS-CoV-2 NP IgA	ELISA 96 Tests	6121	15-04-08-90-00	DE/CA33/AES/2020/1
AESKULISA® SARS-CoV-2 NP IgG	ELISA 96 Tests	6122	15-04-08-90-00	DE/CA33/AES/2020/2
AESKULISA® SARS-CoV-2 NP IgM	ELISA 96 Tests	6123	15-04-08-90-00	DE/CA33/AES/2020/3
AESKULISA® SARS-CoV-2 S1 IgA	ELISA 96 Tests	6124	15-04-08-90-00	DE/CA33/AES/2020/4
AESKULISA® SARS-CoV-2 S1 IgG	ELISA 96 Tests	6125	15-04-08-90-00	DE/CA33/AES/2020/5
AESKULISA® SARS-CoV-2 S1 IgM	ELISA 96 Tests	6126	15-04-08-90-00	DE/CA33/AES/2020/6
AESKU.RAPID SARS-CoV-2 rapid test				
AESKU.RAPID SARS-CoV-2 rapid test	20 Tests	840001	15-04-80-90-00	DE/CA33/AES/2020/7
AESKU.RAPID SARS-CoV-2 rapid test	5 Tests	840003	15-04-80-90-00	DE/CA33/AES/2020/7
AESKU.RAPID SARS-CoV-2 rapid test	2 Tests	840005	15-04-80-90-00	DE/CA33/AES/2020/7
AESKU.RAPID SARS-CoV-2 rapid test	1 Test	840007	15-04-80-90-00	DE/CA33/AES/2020/7
AESKU.COLLECT DBS	Sampling Kit	69610069	26-09	DE/CA33/AES/2021/2
AESKU.COVID19 CHECK	Sampling Kit	861002	26-09	DE/CA33/AES/2021/2
AESKUCARE®				
AESKUCARE® Allergy ONE	ELISA 1 Test	820101	12-02-01-06-00	DE/CA33/AES/2019/25
AESKUCARE® Allergy TWO	ELISA 1 Test	820102	12-02-01-06-00	DE/CA33/AES/2019/25/1
AESKUCARE® Allergy THREE	ELISA 1 Test	820201	12-02-01-06-00	DE/CA33/AES/2019/25/1
AESKUCARE® Allergy FOUR	ELISA 1 Test	820301	12-02-01-06-00	DE/CA33/AES/2019/25/1
AESKUCARE® Food Intolerance ONE	ELISA 1 Test	830101	12-01-01-06-00	DE/CA33/AES/2019/26
AESKUBLOTS®				
AESKUBLOTS® ANA-17 Pro	BLOT 24 Tests	4001	12-10-01-90-00	DE/CA33/AES/2012/1
AESKUBLOTS® Vasculitis Pro	BLOT 24 Tests	4002	12-10-01-03-00	DE/CA33/AES/2012/4
AESKUBLOTS® Myositis Pro	BLOT 24 Tests	4003	12-10-01-90-00	DE/CA33/AES/2012/3
AESKUBLOTS® Liver Pro	BLOT 24 Tests	4004	12-10-90-17-00	DE/CA33/AES/2012/5
AESKUBLOTS® Gastro Pro	BLOT 24 Tests	4005	12-10-90-90-00	DE/CA33/AES/2012/6
AESKUBLOTS® Borrelia-G	BLOT 24 Tests	4006	15-01-06-05-00	DE/CA33/AES/2012/7
AESKUBLOTS® Borrelia-M	BLOT 24 Tests	4007	15-01-06-06-00	DE/CA33/AES/2012/8
AESKUBLOTS® ANA-17 comp	BLOT 24 Tests	4008	12-10-01-90-00	DE/CA33/AES/2017/1
AESKUBLOTS® Allergy ONE	BLOT 24 Tests	421001	12-02-01-06-00	DE/CA33/AES/2019/5/1
AESKUBLOTS® Allergy TWO	BLOT 24 Tests	421002	12-02-01-06-00	DE/CA33/AES/2019/5/1
AESKUBLOTS® Allergy THREE	BLOT 24 Tests	421003	12-02-01-06-00	DE/CA33/AES/2019/5/1
AESKUBLOTS® Allergy FOUR	BLOT 24 Tests	421004	12-02-01-06-00	DE/CA33/AES/2019/5/1
AESKUBLOTS® Allergy FIVE	BLOT 24 Tests	421005	12-02-01-06-00	DE/CA33/AES/2019/5/1
AESKUBLOTS® Allergy SIX	BLOT 24 Tests	421006	12-02-01-06-00	DE/CA33/AES/2019/5/1
AESKUBLOTS® Allergy SEVEN	BLOT 24 Tests	421407	12-02-01-06-00	DE/CA33/AES/2019/5/1
AESKUBLOTS® Allergy EIGHT	BLOT 24 Tests	421408	12-02-01-06-00	DE/CA33/AES/2019/5/1
AESKUBLOTS® Allergy NINE	BLOT 24 Tests	421009	12-02-01-06-00	DE/CA33/AES/2019/5/1

Product	Test	REF	EDMA	Registration Code
AESKUBLOTS® Allergy TEN	BLOT 24 Tests	421010	12-02-01-06-00	DE/CA33/AES/2019/5/1
AESKUBLOTS® Allergy ELEVEN	BLOT 24 Tests	421411	12-02-01-06-00	DE/CA33/AES/2019/5/1
AESKUBLOTS® Allergy TWELVE	BLOT 24 Tests	421412	12-02-01-06-00	DE/CA33/AES/2019/5/1
AESKUBLOTS® Allergy THIRTEEN	BLOT 24 Tests	421413	12-02-01-06-00	DE/CA33/AES/2019/5/1
AESKUBLOTS® Food Intolerance ONE	BLOT 24 Tests	431401	12-01-01-06-00	DE/CA33/AES/2019/18/1
AESKUBLOTS® Food Intolerance TWO	BLOT 24 Tests	431402	12-01-01-06-00	DE/CA33/AES/2019/18/1
AESKUBLOTS® Food Intolerance THREE	BLOT 24 Tests	431403	12-01-01-06-00	DE/CA33/AES/2019/18/1
AESKUBLOTS® Food Intolerance FOUR	BLOT 24 Tests	431404	12-01-01-06-00	DE/CA33/AES/2019/18/1
AESKUBLOTS® Food Intolerance FIVE	BLOT 24 Tests	431405	12-01-01-06-00	DE/CA33/AES/2019/18/1
AESKUBLOTS® Food Intolerance SIX	BLOT 24 Tests	431406	12-01-01-06-00	DE/CA33/AES/2019/18/1
AESKUBLOTS® Food Intolerance SEVEN	BLOT 24 Tests	431407	12-01-01-06-00	DE/CA33/AES/2019/18/1
AESKUSLIDES®				
AESKUSLIDES® ANA HEp-2	KIT 120 Tests	51.100	12-10-01-01-00	DE/CA33/9001/104/1
AESKUSLIDES® ANA HEp-2 Bulk Kit	KIT 600 Tests	51.100.Bulk5	12-10-01-01-00	DE/CA33/9001/104/1
AESKUSLIDES® ANA HEp-2	KIT 120 Tests	51.101	12-10-01-01-00	DE/CA33/9001/104/1
AESKUSLIDES® ANA HEp-2 Bulk Kit	KIT 600 Tests	51.101.Bulk5	12-10-01-01-00	DE/CA33/9001/104/1
AESKUSLIDES® EMA IgA	KIT 50 Tests	512.050	12-10-90-16-00	DE/CA33/9001/109/1
AESKUSLIDES® EMA IgG	KIT 50 Tests	512.060	12-10-90-16-00	DE/CA33/9001/109/1
AESKUSLIDES® EMA IgA	KIT 100 Tests	512.100	12-10-90-16-00	DE/CA33/9001/109/1
AESKUSLIDES® EMA IgG	KIT 100 Tests	512.101	12-10-90-16-00	DE/CA33/9001/109/1
AESKUSLIDES® rLKS wrapped	KIT 50 Tests	517.050	12-10-90-90-00	DE/CA33/9001/107/2
AESKUSLIDES® rLKS separated	KIT 50 Tests	517.051	12-10-90-90-00	DE/CA33/9001/107/2
AESKUSLIDES® rLKS separated	KIT 100 Tests	517.100	12-10-90-90-00	DE/CA33/9001/107/2
AESKUSLIDES® rLKS wrapped	KIT 100 Tests	517.101	12-10-90-90-00	DE/CA33/9001/107/2
AESKUSLIDES® mLKS separated	KIT 50 Tests	518.050	12-10-90-90-00	DE/CA33/9001/108/2
AESKUSLIDES® mLKS separated	KIT 100 Tests	518.100	12-10-90-90-00	DE/CA33/9001/108/2
AESKUSLIDES® nDNA (Crithidia luciliae)	KIT 100 Tests	53.100	12-10-01-05-00	DE/CA33/9001/105/1
AESKUSLIDES® ANCA Ethanol	KIT 60 Tests	54.050	12-10-90-90-00	DE/CA33/AES/2011/1/1
AESKUSLIDES® ANCA Formalin	KIT 60 Tests	54.051	12-10-90-90-00	DE/CA33/AES/2011/1/1
AESKUSLIDES® ANCA Ethanol	KIT 120 Tests	54.100	12-10-90-90-00	DE/CA33/AES/2011/1/1
AESKUSLIDES® ANCA Formalin	KIT 120 Tests	54.101	12-10-90-90-00	DE/CA33/AES/2011/1/1
AESKUSLIDES® ANA HEp-2	IFA	S51.100	12-10-01-01-00	DE/CA33/9001/104/1
AESKUSLIDES® EMA	IFA	S512.050	12-10-90-16-00	DE/CA33/9001/109/1
AESKUSLIDES® EMA	IFA	S512.100	12-10-90-16-00	DE/CA33/9001/109/1
AESKUSLIDES® rLKS wrapped	IFA	S517.050	12-10-90-90-00	DE/CA33/9001/107/2
AESKUSLIDES® rLKS separated	IFA	S517.051	12-10-90-90-00	DE/CA33/9001/107/2
AESKUSLIDES® rLKS separated	IFA	S517.100	12-10-90-90-00	DE/CA33/9001/107/2

Product	Test	REF	EDMA	Registration Code
AESKUSLIDES® rLKS wrapped	IFA	S517.101	12-10-90-90-00	DE/CA33/9001/107/2
AESKUSLIDES® mLKS separated	IFA	S518.050	12-10-90-90-00	DE/CA33/9001/108/2
AESKUSLIDES® mLKS separated	IFA	S518.100	12-10-90-90-00	DE/CA33/9001/108/2
AESKUSLIDES® nDNA (Crithidia luciliae)	IFA	S53.100	12-10-01-05-00	DE/CA33/9001/105/1
AESKUSLIDES® ANCA Ethanol	IFA	S54.050	12-10-90-90-00	DE/CA33/AES/2011/1/1
AESKUSLIDES® ANCA Formalin	IFA	S54.051	12-10-90-90-00	DE/CA33/AES/2011/1/1
AESKUSLIDES® ANCA Ethanol	IFA	S54.100	12-10-90-90-00	DE/CA33/AES/2011/1/1
AESKUSLIDES® ANCA Formalin	IFA	S54.101	12-10-90-90-00	DE/CA33/AES/2011/1/1
AESKUSLIDES® CONJUGATE ANA HEp-2	IFA	C51.100	12-10-01-01-00	DE/CA33/9001/104/1
AESKUSLIDES® CONJUGATE ANA HEp-2 Bulk	IFA	C51.100.Bulk	12-10-01-01-00	DE/CA33/9001/104/1
AESKUSLIDES® CONJUGATE ANA HEp-2	IFA	C51.101	12-10-01-01-00	DE/CA33/9001/104/1
AESKUSLIDES® CONJUGATE ANA HEp-2 Bulk	IFA	C51.101.Bulk	12-10-01-01-00	DE/CA33/9001/104/1
AESKUSLIDES® CONJUGATE EMA IgA	IFA	C512.050	12-10-90-16-00	DE/CA33/9001/109/1
AESKUSLIDES® CONJUGATE EMA IgG	IFA	C512.060	12-10-90-16-00	DE/CA33/9001/109/1
AESKUSLIDES® CONJUGATE nDNA	IFA	C53.100	12-10-01-05-00	DE/CA33/9001/105/1
AESKUSLIDES® CONJUGATE ANCA Ethanol	IFA	C54.050	12-10-90-90-00	DE/CA33/AES/2011/1/1
AESKUSLIDES® CONJUGATE ANCA Formalin	IFA	C54.051	12-10-90-90-00	DE/CA33/AES/2011/1/1
AESKUSLIDES® CONJUGATE ANCA Ethanol	IFA	C54.100	12-10-90-90-00	DE/CA33/AES/2011/1/1
AESKUSLIDES® CONJUGATE ANCA Formalin	IFA	C54.101	12-10-90-90-00	DE/CA33/AES/2011/1/1
AESKUSLIDES® CONJUGATE LKS	IFA	CDTIFA	12-10-90-90-00	DE/CA33/9001/107/2
AESKUSLIDES® CONJUGATE LKS	IFA	CDTIFA.5	12-10-90-90-00	DE/CA33/9001/107/2
AESKUSLIDES® ANCA NEGATIVE CONTROL	IFA	NCANCA	12-10-90-90-00	DE/CA33/AES/2011/1/1
AESKUSLIDES® IFA NEGATIVE CONTROL	IFA	NCIFA	12-10-01-01-00	DE/CA33/9001/104/1
AESKUSLIDES® ANA PATTERN CONTROL (Homogeneous)	IFA	PC51.100	12-10-01-01-00	DE/CA33/9001/104/1
AESKUSLIDES® ANA PATTERN CONTROL (Homogeneous)	IFA	PC51.101	12-10-01-01-00	DE/CA33/9001/104/1
AESKUSLIDES® EMA POSITIVE CONTROL IgA	IFA	PC512.050	12-10-90-16-00	DE/CA33/9001/109/1
AESKUSLIDES® EMA POSITIVE CONTROL IgG	IFA	PC512.060	12-10-90-16-00	DE/CA33/9001/109/1
AESKUSLIDES® AMA positive control 0.5 mL	IFA	PC517.050	12-10-90-90-00	DE/CA33/9001/107/2
AESKUSLIDES® nDNA POSITIVE CONTROL	IFA	PC53.100	12-10-01-05-00	DE/CA33/9001/105/1
AESKUSLIDES® C-ANCA PATTERN CONTROL	IFA	PC54.100	12-10-90-90-00	DE/CA33/AES/2011/1/1
AESKUSLIDES® P-ANCA PATTERN CONTROL	IFA	PC54.101	12-10-90-90-00	DE/CA33/AES/2011/1/1
AESKUSLIDES® AMA POSITIVE CONTROL	IFA	PCDTIFA	12-10-90-90-00	DE/CA33/9001/107/2
AESKUSLIDES® COUNTERSTAIN (Evans Blue 0.2%)	IFA	EBIFA	12-10-90-16-00	DE/CA33/9001/109/1
AESKUSLIDES® MOUNTING MEDIUM	IFA	MMIFA	12-10-01-01-00	DE/CA33/9001/104/1
AESKUSLIDES® MOUNTING MEDIUM Bulk	IFA	MMIFA.Bulk	12-10-01-01-00	DE/CA33/9001/104/1
AESKUSLIDES® SAMPLE BUFFER	IFA	SBIFA	12-10-01-01-00	DE/CA33/9001/104/1
AESKUSLIDES® WASH BUFFER	IFA	WBIFA	12-10-01-01-00	DE/CA33/9001/104/1

Product	Test	REF	EDMA	Registration Code
AESQC®				
AESQC® Pool 1	MULTIPARAMETRIC CONTROLS	AESQCP1	12-50-01-14-00	DE/CA33/AES/2009/1
AESQC® Pool 2	MULTIPARAMETRIC CONTROLS	AESQCP2	12-50-01-14-00	DE/CA33/AES/2009/1
AESQC® Pool 3	MULTIPARAMETRIC CONTROLS	AESQCP3	12-50-01-14-00	DE/CA33/AES/2009/1
AESQC® Pool 4	MULTIPARAMETRIC CONTROLS	AESQCP4	12-50-01-14-00	DE/CA33/AES/2009/1
AESQC® Pool 5	MULTIPARAMETRIC CONTROLS	AESQCP5	12-50-01-14-00	DE/CA33/AES/2009/1
AESQC® Pool 6	MULTIPARAMETRIC CONTROLS	AESQCP6	15-50-01-01-00	DE/CA33/AES/2016/2
AESQC® Pool 7	MULTIPARAMETRIC CONTROLS	AESQCP7	15-50-01-01-00	DE/CA33/AES/2016/3
AESQC® Pool Mix	MULTIPARAMETRIC CONTROLS	AESQCPM	12-50-01-14-00	DE/CA33/AES/2009/1
AESQC® IFA Negative Control	MULTIPARAMETRIC CONTROLS	AESQCFANEG	12-50-01-14-00	DE/CA33/AES/2019/1
AESQC® ANA HEP-2 Homogeneous	MULTIPARAMETRIC CONTROLS	AESQCANA01	12-50-01-14-00	DE/CA33/AES/2019/1
AESQC® ANA HEP-2 Centromere	MULTIPARAMETRIC CONTROLS	AESQCANA03	12-50-01-14-00	DE/CA33/AES/2019/1
AESQC® ANA HEP-2 Speckled	MULTIPARAMETRIC CONTROLS	AESQCANA04	12-50-01-14-00	DE/CA33/AES/2019/1
AESQC® ANA HEP-2 Nucleolar	MULTIPARAMETRIC CONTROLS	AESQCANA09	12-50-01-14-00	DE/CA33/AES/2019/1
AESQC® ANA HEP-2 Cytoplasmic	MULTIPARAMETRIC CONTROLS	AESQCANA21	12-50-01-14-00	DE/CA33/AES/2019/1
AESQC® ANA HEP-2 Panel 1	MULTIPARAMETRIC CONTROLS	AESQCIFANAP1	12-50-01-14-00	DE/CA33/AES/2019/1
SOFTWARE				
HERA	DATA MANAGEMENT SOFTWARE	HER-1000	27-02	DE/CA72/MZ/17/2019



Dr. Torsien Mathias
Dr. Torsien Mathias
CEO

Aesku.Diagnostics GmbH & Co. KG

Wendelsheim, 2021-12-01

Ort, Datum / place, date