Wir; ***GA Generic Assays GmbH, Ludwig-Erhard-Ring 3, 15827 Dahlewitz, Deutschland***; erklären in alleiniger Verantwortung, dass die Medizinprodukte für die In-vitro Diagnostik (siehe Anhang) allen Anforderungen der Richtlinie 98/79/EG entsprechen. Das Konformitätsbewertungsverfahren wurde nach Annex III Absatz 2 durchgeführt. Die folgenden wichtigsten normativen Anforderungen sind, soweit anwendbar, implementiert.

We; ***GA Generic Assays GmbH, Ludwig-Erhard-Ring 3, 15827 Dahlewitz, Germany***; declare under our sole responsibility that the medical devices for in vitro diagnostics (see appendix) comply with all requirements of Directive 98/79/EC. The conformity assessment procedure was carried out according to Annex III, paragraph 2. The following main normative requirements are implemented where applicable.

Nous, ***GA Generic Assays GmbH, Ludwig-Erhard-Ring 3, 15827 Dahlewitz, Allemagne***; déclarons sous notre seule responsabilité que les dispositifs médicaux de diagnostic in vitro (voir annexe) sont conformes à toutes les exigences de la Directive 98/79/CE. La procédure d'évaluation de la conformité a été effectuée conformément à l'annexe III, paragraphe 2. Les principales exigences normatives suivantes sont mises en œuvre, le cas échéant.

Noi, ***GA Generic Assays GmbH, Ludwig-Erhard-Ring 3, 15827 Dahlewitz, Germania***, dichiariamo sotto la nostra esclusiva responsabilità che i dispositivi medici per la diagnosi in vitro (vedi appendice) sono conformi a tutti i requisiti della direttiva 98/79/CE. La procedura di valutazione della conformità è stata effettuata conformemente all'allegato III, paragrafo 2. I seguenti requisiti normativi principali sono attuati ove applicabile.

Nosotros; ***GA Generic Assays GmbH, Ludwig-Erhard-Ring 3, 15827 Dahlewitz, Alemania***; declaramos bajo nuestra exclusiva responsabilidad que los dispositivos médicos para el diagnóstico in vitro (ver anexo) cumplen con todos los requisitos de la Directiva 98/79/CE. El procedimiento de evaluación de la conformidad se llevó a cabo de conformidad con el apartado 2 del anexo III. Los siguientes requisitos normativos principales se aplican cuando procede.

Мы, ***GA Generic Assays GmbH, Ludwig-Erhard-Ring 3, 15827 Dahlewitz, Германия***, заявляем под собственную ответственность, что медицинские продукты для диагностики в лабораторных условиях (смотрите в прикреплённом файле) соответствуют всем требованиям директивы 98/79/EG. Процедура оценки соответствия была проведена в соответствии с пунктом 2 Приложения III. Там, где это применимо, применяются следующие основные нормативные требования.

| Anwendbare Normen<br>Applicable Standards<br>Normes applicables<br>Normas vigentes<br>Norme vigenti<br>Применимые стандарты | Titel<br>Title<br>Título<br>Título<br>Titolo<br>титул |
|---|---|
| EN ISO 13485:2016 | Medizinprodukte – Qualitätsmanagementsysteme – Anforderungen für regulatorische Zwecke<br>Medical devices - Quality management systems – Requirements for regulatory purposes |
| EN 13612:2002 | Leistungsbewertung von In-vitro-Diagnostika<br>Performance evaluation of in vitro diagnostic medical devices |
| EN ISO 14971:2012 | Medizinprodukte – Anwendung des Risikomanagements auf Medizinprodukte<br>Medical devices – Application of risk management to medical devices |
| EN ISO 15223-1:2017 | Medizinprodukte – Bei Aufschriften von Medizinprodukten zu verwendende Symbole, Kennzeichnung und zu liefernde Informationen – Teil 1: Allgemeine Anforderungen<br>Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements |
| EN ISO 17511:2003 | In-vitro Diagnostika – Messung von Größen in Proben biologischen Ursprungs – Metrologische Rückführbarkeit von Werten, die Kalibriermaterialien und Kontrollmaterialien zugeordnet sind<br>In vitro diagnostic medical devices - Measurement of quantities in biological samples – Metrological traceability of values assigned to calibrators and control materials |
| EN ISO 18113-1:2013 | In-vitro-Diagnostika – Bereitstellung von Informationen durch den Hersteller – Teil 1: Begriffe und allgemeine Anforderungen<br>In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements |
| EN ISO 18113-2:2013 | In-vitro-Diagnostika – Bereitstellung von Informationen durch den Hersteller – Teil 2: In-vitro-diagnostische Reagenzien für den Gebrauch durch Fachpersonal<br>In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use |
| EN ISO 18113-3:2013 | In-vitro-Diagnostika – Bereitstellung von Informationen durch den Hersteller – Teil 3: Geräte für in-vitro-diagnostische Untersuchungen zum Gebrauch durch Fachpersonal<br>In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use |
| EN ISO 23640 | In-vitro-Diagnostika – Haltbarkeitsprüfung von Reagenzien für in-vitro-diagnostische Untersuchungen<br>In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents |
| EN ISO 62366:2008 | Medizinprodukte: Anwendung der Gebrauchstauglichkeit auf Medizinprodukte<br>Medical devices: Application of usability engineering to medical devices |
| EN 60601-1:2013 | Medizinisch elektrische Geräte – Teil1: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale<br>Medical electrical equipment – Part 1: General requirements for basic safety and essential performance |

Dahlewitz, Germany; 03.11.2020

GA GENERIC ASSAYS GMBH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow / OT Dahlewitz
Tel: +49(0)33708 / 9286-0
Fax: +49(0)33708 / 4417-25
Email: info@genericassays.com

Prof. Dr. Dirk Roggenbuck; CEO,
GA Generic Assays GmbH

# Appendix

Valid from: 03.11.2020

| Product | Article-No. | EDMS code | Classification |
|---|---|---|---|
| ***ELISA*** | | | |
| Anti-ASGPR | 3900 | 12-10-90-90-00 | Other device |
| ASCA IgA | 4006 | 12-10-90-19-00 | Other device |
| ASCA IgG | 4007 | 12-10-90-19-00 | Other device |
| ANA screen | 4010 | 12-10-01-01-00 | Other device |
| ENA screen | 4011 | 12-10-01-02-00 | Other device |
| ANApro | 4012 | 12-10-01-01-00 | Other device |
| ENAcombi | 4234 | 12-10-01-02-00 | Other device |
| Anti-Cardiolipin screen | 4014 | 12-10-90-01-00 | Other device |
| Anti-dsDNA | 4015 | 12-10-01-05-00 | Other device |
| Anti-Cardiolipin | 4016 | 12-10-90-01-00 | Other device |
| RF IgA | 4027 | 12-11-01-10-00 | Other device |
| Anti-huTransG | 4033 | 12-10-90-22-00 | Other device |
| Anti-LC1 | 4054 | 12-10-90-90-00 | Other device |
| CeliAK EmA human | 4035 | 12-10-90-22-00 | Other device |
| Anti-ß2-GP-I Screen | 4036 | 12-10-90-01-00 | Other device |
| Anti-ß2-GP-I | 4041 | 12-10-90-04-00 | Other device |
| Anti-hu tTG IgG | 4044 | 12-10-90-22-00 | Other device |
| CeliAK EmA human IgG | 4045 | 12-10-90-22-00 | Other device |
| RF IgM | 4046 | 12-11-01-10-00 | Other device |
| Anti-Phospholipid screen | 4050 | 12-10-90-90-00 | Other device |
| Anti-M2 | 4052 | 12-10-90-02-00 | Other device |
| Anti-LKM-1 | 4053 | 12-10-90-08-00 | Other device |
| Anti-Phosphatidyl-Serin | 4056 | 12-10-90-03-00 | Other device |
| Anti-MPO | 4058 | 12-10-90-09-00 | Other device |
| Anti-PR3 | 4059 | 12-10-90-10-00 | Other device |
| RF IgG | 4085 | 12-11-01-10-00 | Other device |
| GliaDea IgA | 3710 | 12-10-90-06-00 | Other device |
| GliaDea IgG | 3810 | 12-10-90-06-00 | Other device |
| Helicobacter pylori Antigen | 6012/6013 | 15-01-04-01-00 | Other device |
| Anti-GP2 IgG | 3850 | 12-10-90-90-00 | Other device |
| Anti-GP2 IgA | 3750 | 12-10-90-90-00 | Other device |
| Anti-Faktor H | 4067 | 12-01-02-90-00 | Other device |
| Anti-Intrinsic Factor | 3600 | 12-10-90-90-00 | Other device |
| Anti-GPC | 3610 | 12-10-90-11-00 | Other device |
| Pancreatitis GP2 | 3950 | 12-06-90-90-00 | Other device |
| GA CoV-2 IgG | 3920 | 15-04-80-90-00 | Other device |
| GA CoV-2 IgG + | 3940 | 15-04-80-90-00 | Other device |
| GA CoV-2 IgM | 3930 | 15-04-80-90-00 | Other device |
| ***LINE Immunoassay*** | | | |
| BiermAK LINE | 4220 | 12-10-90-11-00 | Other device |

| Product | Article-No. | EDMS code | Classification |
|---|---|---|---|
| ANA 12 LINE | 4289 | 12-10-01-01-00 | Other device |
| ANA 18 LINE | 4291 | 12-10-01-01-00 | Other device |
| CeliAK IgA LINE | 4208 | 12-10-90-22-00 | Other device |
| CeliAK IgG LINE | 4202 | 12-10-90-22-00 | Other device |
| Anti-Gangliosid Dot | 5003 | 12-10-02-01-00 | Other device |
| Anti-Phospholipid Dot | 5006 | 12-10-90-01-00 | Other device |
| Anti-Phospholipid 10 Dot | 5012 | 12-10-90-01-00 | Other device |
| ANCA Dot | 4028 | 12-10-90-90-00 | Other device |
| HepAK Dot | 4029 | 12-10-90-08-00 | Other device |
| HepAK$^{plus}$ Dot | 4030 | 12-10-90-08-00 | Other device |
| PMScl$^{plus}$ Dot | 4049 | 12-10-10-01-00 | Other device |
| ANAscl$^{plus}$ Dot | 4074 | 12-10-01-90-00 | Other device |
| ENA Dot | 4077 | 12-10-01-02-00 | Other device |
| HepAK 7 plus Dot | 4099 | 12-10-90-08-00 | Other device |
| ***Automated LINE Immunoassays*** | | | |
| DotDiver CeliAK IgA | 5014 | 12-10-90-22-00 | Other device |
| DotDiver CeliAK IgG | 5015 | 12-10-90-22-00 | Other device |
| DotDiver ANA | 5016 | 12-10-01-01-00 | Other device |
| DotDiver PmScl | 5017 | 12-10-01-10-00 | Other device |
| DotDiver ANCA | 5018 | 12-10-90-90-00 | Other device |
| DotDiver BiermAK | 5019 | 12-10-90-10-00 | Other device |
| DotDiver Quantrix ANA | 5020 | 12-10-01-01-00 | Other device |
| DotDiver HepAK 7 plus | 5021 | 12-10-90-08-00 | Other device |
| DotDiver ANA PCNA | 5035 | 12-10-90-90-00 | Other device |
| DotDiver Lupus | 5029 | 12-10-90-90-00 | Other device |
| DotDiver PmScl 12 | 5045 | 12-10-10-01-00 | Other device |
| DotDiver Anti-Gangliosid IgG | 50381 | 12-10-02-01-00 | Other device |
| DotDiver Anti-Gangliosid IgM | 50391 | 12-10-02-01-00 | Other device |
| DotDiver Anti-Gangliosid screen | 50301 | 12-10-02-01-00 | Other device |
| DotDiver Anti-Phospholipid IgG | 50401 | 12-10-90-90-00 | Other device |
| DotDiver Anti-Phospholipid IgM | 50411 | 12-10-90-90-00 | Other device |
| DotDiver Myositis 12 | 5093 | 12-10-90-90-00 | Other device |
| DotDiver ANAcyto 10 | 5066 | 12-10-01-90-00 | Other device |
| DotDiver Scleroderma 10 | 5069 | 12-10-01-90-00 | Other device |
| DotDiver HepAK 10 | 5070 | 12-10-90-08-00 | Other device |
| ***Rapid Tests*** | | | |
| Anti-Streptolysin-O Latex | 3003 | 12-11-01-05-00 | Other device |
| CRP Latex | 4095 | 12-11-01-09-00 | Other device |
| RF Latex | 4096 | 12-11-01-10-00 | Other device |
| Rotavirus Antigen Quick | 6101 | 15-04-80-06-00 | Other device |
| Adenovirus Antigen Quick | 6102 | 15-04-80-01-00 | Other device |
| Rotadeno Antigen Quick | 6103 | 15-04-80-01-00 | Other device |
| Influenza Antigen Quick | 6109 | 15-04-80-04-00 | Other device |

| Product | Article-No. | EDMS code | Classification |
|---|---|---|---|
| Helicobacter Antigen Quick | 6110 | 15-01-04-01-00 | Other device |
| D-Dimer Latex | 3021/3321 | 13-02-70-03-00 | Other device |
| Helicobacter Antigen Quick | 6112 | 15-01-04-01-00 | Other device |
| GA CoV-2 Antigen Rapid | 3980 | 15-04-80-90-00 | Other device |
| ***Immunofluorescence Assays*** | | | |
| nDNA IFA plus (60 Determination) | 81050 | 12-10-01-05-00 | Other device |
| nDNA IFA plus (120 Determination) | 81100 | 12-10-01-05-00 | Other device |
| AMA IFA | 83048 | 12-10-90-02-00 | Other device |
| ASMA IFA | 84048 | 12-10-01-90-00 | Other device |
| Triple IFA (48 Determination) | 85048 | 12-10-90-90-00 | Other device |
| Triple IFA (96 Determination) | 85096 | 12-10-90-90-00 | Other device |
| Triple IFA Plus | 8176 | 12-10-90-90-00 | Other device |
| AAA IFA | 85648 | 12-10-90-90-00 | Other device |
| ICA IFA | 85848 | 12-06-01-09-00 | Other device |
| EmA IFA (48 Determination) | 86048 | 12-10-90-16-00 | Other device |
| EmA IFA (96 Determination) | 86096 | 12-10-90-16-00 | Other device |
| ASA IFA | 86148 | 12-10-90-90-00 | Other device |
| CMA IFA | 86248 | 12-10-90-90-00 | Other device |
| SkMA IFA | 86348 | 12-10-90-90-00 | Other device |
| Anti-GBM IFA | 86448 | 12-10-90-15-00 | Other device |
| ANA Hep-2 plus | 81040/8101 | 12-10-01-01-00 | Other device |
| cANCA IFA plus | 87061 | 12-10-90-10-00 | Other device |
| pANCA IFA plus | 87161 | 12-10-90-09-10 | Other device |
| Anti-MuSK IFA | 8049 | 12-10-90-90-00 | Other device |
| CytoBead ANCA | 8063 | 12-10-90-90-00 | Other device |
| CytoBead CeliAK | 8064 | 12-10-90-22-00 | Other device |
| CytoBead ANA | 8065 | 12-10-01-01-00 | Other device |
| CytoBead ANA 2 | 8220 | 12-10-01-01-00 | Other device |
| CytoBead RPGN | 8066 | 12-10-90-90-00 | Other device |
| ***Automatic Devices*** | | | |
| DotDiver2.0 | 5075 | 22-03-03 | Other device |