

Memo

IVDR statement

To: Recipient
From: W. Glas

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Sanquin Diagnostiek B.V.
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Sanquin Diagnostic Services, also known by its tradename Sanquin Diagnostiek B.V, uses CE certified devices & kits to perform diagnostic services for third parties. However, in a minority of cases, in-house developed tests are used to comply to specific needs of the target patient group. For these in-house tests, Sanquin Diagnostiek B.V, declares:

- Tests are executed under ISO 15189. This means that in-house developed diagnostic tests are validated and executed as per ISO 15189. This also is true for CE certified bought kits which are modified by Sanquin.
- These diagnostic devices meet the relevant general safety and performance requirements as described in Annex I of European Regulation 2017/746 on in vitro diagnostic medical devices.
- Deviations from Annex I of European Regulation 2017/746 on in vitro diagnostic medical devices and its justifications are documented in our quality documentation, referred to as 'dossier'.

Description

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| Dossier IVDR Biologics Anti-Drug Antibodies | D-DOS-0024 |
| Dossier IVDR Biologics spiegel ELISA's | D-DOS-0023 |
| Dossier MAIGA | D-DOS-0022 |
| IVDR dossier Lactose Intolerantie Test | D-DOS-0021 |
| Dossier MAIPA | D-DOS-0020 |
| Dossier Heparin Induced Platelet Activation Assay (HIPAA) | D-DOS-0019 |
| Dossier Trombopoietinebepaling (ELISA) | D-DOS-0018 |
| AET behandelen van erythrocyten t.b.v. uitsluiten van allo antistoffen bij patiënten behandeld met Anti CD38 | D-DOS-0017 |
| Genotypering van bloedgroep, HPA en HNA genen en het DPYD-gen m.b.v. Taqman allelische discriminatie | D-DOS-0016 |
| Dossier G6PD dragerschap dmv de FACS | D-DOS-0015 |
| IVDR dossier Foetale bloedgroep typering en gender typering in maternaal plasma met de ddPCR | D-DOS-0014 |
| IVDR dossier Screening foetale RHD genotypering | D-DOS-0013 |
| Dossier Sikkelprecipitatietest | D-DOS-0012 |
| Dossier Hemoglobine scheiding op HPLC | D-DOS-0011 |
| Dossier Neutraliserende antistoffen tegen C1-esteraseremmer met behulp van ELISA | D-DOS-0010 |
| IVDR dossier conform EU verordening 2017/746 mbt de antistof-afhankelijke cellulaire cytotoxiciteitstest (ADCC test) | D-DOS-0009 |
| Dossier CDC testen | D-DOS-0008 |
| Dossier EMA bepaling | D-DOS-0007 |
| Dossier AGLT | D-DOS-0006 |
| Dossier alfa-thalassemie multiplex methode | D-DOS-0005 |
| Dossier hemochromatose TaqMan bepaling | D-DOS-0004 |
| Dossier Spectrine bepaling | D-DOS-0003 |
| Dossier enzymbepaling | D-DOS-0002 |
| CLIS Dossier | DR-DOS-0002 |