Device Schedule: Class D, C and B devices

Class D devices	Intended Purpose
cobas® HEV-96	See EU Technical Documentation Assessment Certificate IVDR 732823
cobas® HEV-192	See EU Technical Documentation Assessment Certificate IVDR 732823
cobas® HEV Control Kit	See EU Technical Documentation Assessment Certificate IVDR 732823
cobas® Babesia - 480	See EU Technical Documentation Assessment Certificate IVDR 732837
cobas® Babesia Control Kit	See EU Technical Documentation Assessment Certificate IVDR 732837
cobas® CHIKV/DENV - 480	See EU Technical Documentation Assessment Certificate IVDR 732838
cobas® CHIKV/DENV Control Kit	See EU Technical Documentation Assessment Certificate IVDR 732838
cobas® WNV - 192	See EU Technical Documentation Assessment Certificate IVDR 732831
cobas® WNV - 480	See EU Technical Documentation Assessment Certificate IVDR 732831
cobas® WNV Control Kit	See EU Technical Documentation Assessment Certificate IVDR 732831
cobas® DPX- 96	See EU Technical Documentation Assessment Certificate IVDR 732829
cobas® DPX- 192	See EU Technical Documentation Assessment Certificate IVDR 732829
cobas® DPX Control Kit	See EU Technical Documentation Assessment Certificate IVDR 732829
cobas® Zika - 480	See EU Technical Documentation Assessment Certificate IVDR 732833

Class D devices	**Intended Purpose**
cobas® Zika Control Kit	See EU Technical Documentation Assessment Certificate IVDR 732833
cobas® SARS-CoV-2 Qualitative 192T	See EU Technical Documentation Assessment Certificate IVDR 752735
cobas® SARS-CoV-2 Qualitative 480T	See EU Technical Documentation Assessment Certificate IVDR 752735
cobas® SARS-CoV-2 Qualitative Control Kit	See EU Technical Documentation Assessment Certificate IVDR 752735
cobas® SARS-CoV-2 Duo	See EU Technical Documentation Assessment Certificate IVDR 782480
cobas® SARS-CoV-2 Duo Control Kit	See EU Technical Documentation Assessment Certificate IVDR 782480
cobas® MPX - 480	See EU Technical Documentation Assessment Certificate IVDR 732739
cobas® MPX - 192	See EU Technical Documentation Assessment Certificate IVDR 732739
cobas® MPX Control Kit	See EU Technical Documentation Assessment Certificate IVDR 732739
cobas® NHP Negative Control Kit	See EU Technical Documentation Assessment Certificate IVDR 732739
cobas® HIV-1	See EU Technical Documentation Assessment Certificate IVDR 732824
cobas® HIV-1/HIV-2 Qualitative	See EU Technical Documentation Assessment Certificate IVDR 732825
cobas® HIV-1/HIV-2 Qualitative Control Kit	See EU Technical Documentation Assessment Certificate IVDR 732825
cobas® Malaria - 192	See EU Technical Documentation Assessment Certificate IVDR 791536
cobas® Malaria Control Kit	See EU Technical Documentation Assessment certificate IVDR 791536
cobas® HCV	See EU Technical Documentation Assessment Certificate IVDR 732822

Class D devices	**Intended Purpose**
cobas® HBV	See EU Technical Documentation Assessment Certificate IVDR 732821
cobas® Respiratory flex	See EU Technical Documentation Assessment Certificate IVDR 804022
cobas® Respiratory flex Control Kit	See EU Technical Documentation Assessment Certificate IVDR 804022
cobas® HBV/HCV/HIV-1 Control kit	See EU Technical Documentation Assessment Certificate IVDR 732826

Class D near-patient test devices	**Intended Purpose**
cobas® SARS-CoV-2 Nucleic acid test for use on the cobas® Liat® System	See EU Technical Documentation Assessment Certificate IVDR 752731
cobas® SARS-CoV-2 Quality Control Kit for use on the cobas® Liat® System	See EU Technical Documentation Assessment Certificate IVDR 752731
cobas® SARS-CoV-2 & Influenza A/B nucleic acid test for use on the cobas® Liat® System	See EU Technical Documentation Assessment Certificate IVDR 752726
cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit for use on the cobas® Liat® System	See EU Technical Documentation Assessment Certificate IVDR 752726

Class C devices	**Intended Purpose**
W0105 – infectious immunology **IVP3011** – *in vitro* diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays	Nucleic Acid Devices intended to be used for confirmation or identification of infectious agents and screening of cervical cancer
W0106 - genetic testing **IVP3011 -** *in vitro* diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid devices	Nucleic acid device intended for genotyping patients as an aid for diagnosing suspected thrombophilia

Class C near-patient test devices	**Intended Purpose**
cobas® liat CT/NG/MG	See EU Technical Documentation Assessment Certificate IVDR 802289
cobas® liat CT, NG and MG control kit	See EU Technical Documentation Assessment Certificate See IVDR 805377
cobas® liat CT/NG	See EU Technical Documentation Assessment Certificate See IVDR 802291
cobas® liat Bordetella panel	See EU Technical Documentation Assessment Certificate IVDR 816492
cobas® liat Bordetella panel control kit	See EU Technical Documentation Assessment Certificate IVDR 816492

Class B near-patient test devices	**Intended Purpose**
cobas® Strep A Nucleic acid test for use on the cobas® Liat® System	See EU Technical Documentation Assessment Certificate IVDR 732757
cobas® Strep A Quality Control Kit for use on the cobas® Liat® System	See EU Technical Documentation Assessment Certificate IVDR 732757
cobas® Influenza AB & RSV Nucleic acid test for use on the cobas® Liat® System	See EU Technical Documentation Assessment Certificate IVDR 732839
cobas® Influenza A/B & RSV Quality Control Kit for use on the cobas® Liat® System	See EU Technical Documentation Assessment Certificate IVDR 732839
cobas® Cdiff Nucleic acid test for use on the cobas® Liat® System	See EU Technical Documentation Assessment Certificate IVDR 749724
cobas® Cdiff Positive and Negative Control Kit for use on the cobas® Liat® System	See EU Technical Documentation Assessment Certificate IVDR 749724
cobas® liat SARS-CoV-2, Influenza A/B & RSV nucleic acid test	See EU Technical Documentation Assessment Certificate IVDR 816493
cobas® liat SARS-CoV-2 & Influenza A/B v2 nucleic acid test	See EU Technical Documentation Assessment Certificate IVDR 816494
cobas® liat SARS-CoV-2, v2 nucleic acid test	See EU Technical Documentation Assessment Certificate IVDR 816495

Class B near-patient test devices	Intended Purpose
cobas® liat SARS-CoV-2, Influenza A/B & RSV control kit	See EU Technical Documentation Assessment Certificate IVDR 816496

Class B devices	Intended Purpose
IVR0503 – Devices intended to be used to detect the presence of, or exposure to infectious agent.	Nucleic acid devices intended to be used for the qualitative detection, or exposure to an infectious agent.

Device Schedule: Class A sterile devices

Device(s)	Risk Classification
IVR 0803 – Sterile Specimen Receptacles	Class As
For Class A sterile devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	