Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Defence,
Civil Protection and Sport DDPS

Federal Office for Civil Protection FOCP
Spiez Laboratory

Spiez Laboratory

Public declaration of devices manufactured and used internally (LDTs)

Name of the laboratory — Spiez Laboratory

Address — Austrasse, 3700 SPIEZ

Spiez Laboratory declares that the devices described in the attached table are only manufactured and used in its laboratories and meet the General Safety and Performance Requirement (GSPR) for medical devices (EU2017/745) or the Art. 5, para 5, lit. f of the Regulation (EU) 2017/746 on in vitro diagnostic medical devices. A justification is provided in case the applicable requirements safety and performance requirements are not fully met.

Spiez, 28.05.2025 — Dr. Kristina Schmidt

Name of the device	Type (IVD/MD)	Risk classification acc. to IVDR	Destination	Do the device meet the GSPR requirements)	Information and justification regarding applicable GSP not fully met (using the numbering of the annexe 1 of the IVDR/MDR)
Crimean-Congo haemorrhagic fever virus PCR	IVD	D	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
Ebolaviruses PCR	IVD	D	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
Hantaviruses PCR	IVD	D	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
Lassa virus PCR	IVD	D	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
Marburg virus PCR	IVD	D	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
Orthopoxvirus PCR	IVD	D	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test

Name of the device	Type (IVD/MD)	Risk classification acc. to IVDR	Destination	Do the device meet the GSPR requirements)	Information and justification regarding applicable GSP not fully met (using the numbering of the annexe 1 of the IVDR/MDR)
Bacillus anthracis PCR	IVD	C	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
Brucella spp/melitensis PCR	IVD	C	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
Burkholderia pseudomallei PCR	IVD	C	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
Coxiella burnetii PCR	IVD	C	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
Francisella tularensis PCR	IVD	C	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
Yersinia pestis PCR	IVD	C	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
Equine Encephalitis Virus (EEEV, WEEV, VEEV) PCR	IVD	C	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
Guanarito Virus PCR	IVD	C	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
Hendra Virus PCR	IVD	C	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
Japanese Encephalitis Virus PCR	IVD	C	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
Junin Virus PCR	IVD	C	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
Machupo Virus PCR	IVD	C	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test

Name of the device	Type de dispositif (IVD/MD)	Risk classification acc. to IVDR	Destination	Do the device meet the GSPR requirements)	Information and justification regarding applicable GSP not fully met (using the numbering of the annexe 1 of the IVDR/MDR)
MERS Coronavirus PCR	IVD	C	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
Nipah virus PCR	IVD	C	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
Sabia Virus PCR	IVD	C	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
SARS -CoV-1 PCR	IVD	C	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
SARS-CoV-2 (COVID-19) PCR	IVD	C	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
St. Louis Encephalitis Virus PCR	IVD	C	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test
West-Nile Virus PCR	IVD	C	Qualitative detection of the pathogen	YES	Analytical performance (9.1). Few positive specimens available for the validation of the test