Public Declaration Regarding the Manufacture and Use of In-House Devices by Health Institutions

Name of Health Institution: Precision for Medicine GmbH

Address: Barbara-McClintock-Str. 6 · 12489 Berlin Germany

Precision for Medicine GmbH declares that the devices described in the accompanying table are only manufactured and used in **Precision for Medicine GmbH** and do meet the applicable general safety and performance requirements (GSPR) of the in vitro diagnostic medical devices Regulation (EU 2017/746). A reasoned justification is provided in case applicable general safety and performance requirements are not fully met.

Date and location: **Berlin,** 13-Okt-2026

Name: **Sven Olek**

Function: **Managing Director Lab Management & Operations**

Signature of responsible person(s):

Signiert von:
Sven Olek
Name des Unterzeichners: Sven Olek
Signiergrund: Ich genehmige dieses Dokument
Signierzeit: 13-Okt-2026 | 7:23:38 AM PDT
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Device identification (e.g., name, description, reference number)	Device type	Risk class of the device	Intended purpose	Applicable GSPR fully met? (Y/N)	Information on and justification for applicable GSPR that are not fully met (using the numbering as in Annex I of the IVDR
FOXP3/CD3	IVD	C	The EpiontisID FOXP3/CD3 Treg Quantification test is a quantitative, real-time PCR-based in vitro diagnostic test intended to determine the percentage of CD3-demethylated T cells that are also demethylated in the regulatory T-cell-specific demethylated region of the FOXP3 gene in human whole blood. The test is intended to aid in the diagnosis of patients with suspected congenital regulatory T-cell-related immunodeficiencies, including FOXP3 deficiency such as IPEX syndrome. Results must be interpreted in conjunction with other clinical and laboratory findings.	Y	Not Applicable

CTLA4/CD3	IVD	C	The EpiontisID CTLA4/CD3 Quantification test is a quantitative, real-time PCR-based in vitro diagnostic test intended to determine the percentage of CD3-demethylated T cells that are also demethylated in the CTLA4 gene in human whole blood. The test is intended to aid in the diagnosis of patients with suspected congenital regulatory T-cell-related immunodeficiencies, including CTLA4 deficiency. Results must be interpreted in conjunction with other clinical and laboratory findings	Y	Not Applicable
FOXP3/CD4	IVD	C	The EpiontisID FOXP3/CD4 Treg Quantification test is a quantitative, real-time PCR-based in vitro molecular diagnostic test intended to determine the percentage of CD4-demethylated T cells that are also demethylated in the regulatory T-cell-specific demethylated region of the FOXP3 gene in human whole blood. The test is intended to facilitate the diagnosis of patients with inborn regulatory T-cell deficiencies, including FOXP3 deficiency such as IPEX syndrome, and may provide indications of other inborn regulatory T-cell disorders. Results must be interpreted in conjunction with other clinical and laboratory findings	Y	Not Applicable

Revision History		
Version	***Date***	***Changes***
Version 1	13OCT2026	Initial release