Public declaration regarding the manufacture and use of in-house devices by health institutions

in accordance with Art. 5 (5) EU Regulation on in vitro diagnostic medical devices (EU) 2017/746 (IVDR) for in-house production of IVD in health institutions and under Art. 5 (5) EU Regulation on medical devices (EU) 2017/745 (MDR) for in-house production of MD in health institutions

Name of health institution: MoKi Analytics GmbH, practice Moter Diagnostics

Address: Marienplatz 9, 12207 Berlin, Germany

MoKi Analytics GmbH and the associated practice Moter Diagnostics declare that the devices described in the accompanying table are manufactured and/or used at MoKi Analytics GmbH, practice Moter Diagnostics and do meet the applicable general safety and performance requirements (GSPR) of the medical devices Regulation (EU 2017/745) or 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: 12. June 2026

Name, function and signature of responsible person(s):

Priv.-Doz. Dr. phil. nat. habil. Judith Kikhney, CEO MoKi Analytics

J. Kikhney

Signed

12.06.2026

Dated

Prof. Dr. med. Annette Moter, Head of Moter Diagnostics

Annette Moter

Signed

12.06.2026

Dated

Table of in-house devices:

Device identification	Device type (IVD / MD)	Risk class of the device	Intended purpose	Applicable GSPR fully met?	Information on and justification for applicable GSPR that are not fully met
FISHopt® fixation solution	IVD	A	Fixation of samples for subsequent FISHseq or Microbiome-guided (MG-) FISH analysis	Yes	NA
Bacteria by FISHseq including Sanger Sequencing	IVD	C	Patient health data	Yes	NA
Bacteria by MG-FISH including massive parallel sequencing (MPS: Illumina or Nanopore Sequencing)	IVD	C	Patient health data	Yes	NA