


DECLARATION OF CONFORMITY

PART A: INFORMATION ABOUT THE MANUFACTURING HEALTH INSTITUTE

Institute / Laboratory	
Name:	Lifespın GmbH
Address:	Am BioPark 13 93053 Regensburg Germany

Contact	
Name:	Customer Service
Telephone Number:	+49 941 942 898 22
E-mail:	customerservice@lifespın.health

Declaration	
Above mentioned institution states for all tests listed in Part B that they are only manufactured and used by this institute and do meet the applicable general safety and performance requirements (GSPR) of the in vitro diagnostic medical devices Regulation (EU 2017/746).	

Signed on behalf of the organization	
Name:	Dr. Fritz Huber
Job Title:	CEO
Date and Location:	08.01.2023, Regensburg
Signature:	 X

PART B: LAB-DEVELOPED TESTS

Pos.	Identification	Intended Purpose	Risk Class (Annex VIII)
1	LDT-A_VI	Generation of NMR-spectra of human serum or plasma samples	B
2	LDT-Profiler_VI	Determination of defined patterns in NMR-spectra	B
3	AminoAcidProfile_VI	Quantification of amino acids and derivates	B
4	LDT-F_VI	Generation of NMR-spectra of human serum samples with precipitation of proteins	B
5	TDM-Antiinfectiva_VI	Quantification of selected antiinfectiva	C