



Declaration of Conformity

Cat.No. Mikrogen:		Certificates valid according to the	Risk classification under the IVDR	Basic UDI-DI
830513	<i>alpha</i> Cube Noro	IVDD	C	426019901G01008HS
830535/ 830536	<i>alpha</i> Cube PanLegionella	IVDD	C	426019901G01020HG
830533/ 830534	<i>alpha</i> Cube Ehrlichia	IVDD	C	426019901G01045HY
830525/ 830526	<i>alpha</i> Cube Babesia	IVDD	C	426019901G01053HX
830527/830528	<i>alpha</i> Cube Borrelia	IVDD	C	426019901G01062HY
830539/ 830540	<i>alpha</i> Cube Legionella	IVDD	C	426019901G01064J4
830519/ 830520	<i>alpha</i> Cube TBE	IVDD	C	426019901G01066J8
830507/830508	<i>alpha</i> Cube respiraRNA 3.0	IVDD	C	426019901G01084JA
830501/830502	<i>alpha</i> Cube gastroplexVirus	IVDD	C	426019901G01086JE
830509/ 830510	<i>alpha</i> Cube Entero 2.0	IVDD	C	426019901G01097JK
830557/ 830558	<i>alpha</i> Cube MRSA 3.0	IVDD	C	426019901G01100HF
830547/ 830548	<i>alpha</i> Cube GBS	IVDD	C	426019901G01101HH
830555/ 830556	<i>alpha</i> Cube Q-Fever	IVDD	C	426019901G01106HT
830561/ 830562	<i>alpha</i> Cube MTB	IVDD	C	426019901G01107HV
830560/ 830559	alphaCube Bordetella	IVDD	C	426019901G01109HZ
830563/ 830564	<i>alpha</i> Cube Tropical Fever 1	IVDD	C	426019901G01110HJ
830503/830504	<i>alpha</i> Cube gastroplexVirus PLUS 2.0	IVDD	C	426019901H01113HQ
830566/830567	<i>alpha</i> Cube MTB/NTM/MAC	IVDD	C	426019901G01114HS
830568/ 830569	alphaCube TBEV/WNV	IVDD	C	426019901G01115HU
830573/ 830572	alphaCube HSV/VZV	IVDD	C	426019901G01116HW
830575/ 830574	alphaCube Rickettsia	IVDD	C	426019901G01118J2
830571/ 830570	alphaCube PVL-MRSA	IVDD	C	426019901G01120HM
830577/ 830576	alphaCube Borrelia/Rickettsia	IVDD	C	426019901G01122HR
830578	alphaCube MRSAseqc	IVDD	C	426019901G01140HT
830579	alphaCube Entero/Rhino	IVDD	C	426019901G01142HX
830580	alphaCube P.jirovecii quant	IVDD	C	426019901G01139JA


We declare under our sole responsibility, that the product mentioned above is in conformity with the requirements of the valid version of the guideline 98/79/EG (attachment III, without III.6) for in-vitro diagnostica.

The product will be marked with the CE-label.

Place and Date:

Kornwestheim, 24.05.2022

Quality Manager:


 Dr. C. Metzger-Boddien