EC Declaration of Conformity

according to annex III, EC Directive 98/79/EF

Manufacturer Name: RefLab Aps

Manufacturer Address: Ole Maaløes Vej 3, COBIS
2200 Copenhagen N
DK-Denmark

Cat. number:	Name of the Device:	Cat. number:	Name of the Device:
BHRA (HR-Test) Plates:			
RLA210	Histamine plate	RLA210.10	Histamine plate. Box of 10
RLA211.1	Customer material plate	RLA211.10	Customer material plate. Box of 10
RLA5CSU	s-BHRA (HR-Urticaria Test) combination		
BHRA (HR-Test) Panels:			
RLA212.1	Inhalation panel	RLA212.10	Inhalation panel. Box of 10
RLA213.1	Food panel	RLA213.1	Food panel. Box of 10
RLA214.1	Dermatology panel	RLA214.1	Dermatology panel. Box of 10

and derived panel composition variants from the allergen range:

F069 Almond	F052 Orange	E006 Cat epithelia
F054 Banana	F015 Peanut	E082 Cockroach
F067 Barley	F087 Peach	E005 Dog epithelia
F041 Beef	F060 Pepper	E033 Guinea pig epithelia
F070 Brazil nut	F045 Plaice	E032 Hamster epithelia
F065 Buckwheat	F042 Pork	E004 Horse epithelia
F056 Carrot	F057 Potato	E031 Rabbit epithelia
F089 Cashew	F068 Rice	E030 Rat epithelia
F019 Celery	F064 Rye	F058 Tomato
F044 Chicken	F078 Salmon	F049 Tuna
F016 Cod Fish	F088 Sesame	M009 Alternaria alternata
F066 Corn	F017 Shrimp	M035 Aspergillus fumigatus
F048 Crab	F018 Soybean	M077 Aspergillus versicolor
F012 Egg white	F053 Strawberry	M022 Baker's yeast
F059 Green bean	F058 Tomato	M037 Botrytis cinerea
F061 Green pea	F049 Tuna	M024 Candida albicans
F014 Hazelnut	F071 Walnut	M010 Cladosporium herbarum
F046 Herring	F013 Wheat flour	M007 Derm pteronyssinus
F020 Kiwi	P026 Alder	M008 Derm farinae
F043 Lamb	P028 Ash	M038 Penicilium expansum
F047 Mackerel	P025 Hazel	M039 Penicillium chrysogenum
F086 Mango	P003 Mugwort	M021 Pityrosporum ovale
F081 Melon	P083 Ragweed	M040 Trichoderma viride
F011 Milk	P001 Silver birch	V073 Bee venom
F079 Mussel / Clam	P002 Timothy grass	V074 Wasp venom
F063 Oat	P100 Platanus acerifolia	O075 Latex
F080 Octopus	P101 Japanese hop	

RefLab ApS
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Notified Body name: N/A

Notified Body Address: N/A

Notified Body Identification number: N/A

Conformity assessment route:

This declaration of conformity is issued under the sole responsibility of RefLab Aps. We hereby declare that the in-vitro diagnostic medical device(s) specified above meet the provision of the EC Directive 98/79/EF, Annex III (IVDD). This declaration is supported by the ISO 13485 Quality Management System approval issued by DQS. All supporting documentation is retained at the premises of the manufacturer.

Signature:

Lise Bo
Quality Manager

Place and date (dd.mm.yyyy) of issue:

Copenhagen, 25.05.2022

RefLab ApS
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