

## EC Declaration of Conformity

<b>Manufacturer Name:</b>	RefLab Aps
<b>Manufacturer Address:</b>	Kanalholmen 1, 2.th DK-2650 Hvidovre Denmark
<b>Notified Body name:</b>	N/A
<b>Notified Body Address:</b>	N/A
<b>Notified Body Identification number:</b>	N/A

*Reflab Aps hereby declares conformity to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices for the following In Vitro Diagnostic Devices:*

Art. no	Name of device	Pack size	Art. no	Name of device	Pack size
RLA211	CM-plate	1	RLA211.10	CM-plate	10
RLA212	Inhalation allergen panel	1	RLA212.10	Inhalation allergen panel	10
RLA213	Food allergen panel	1	RLA213.10	Food allergen panel	10
RLA214	Dermatology allergen panel	1	RLA214.10	Dermatology allergen panel	10
RLA215	Fungi allergen panel	1	RLA215.10	Fungi allergen panel	10
RLA220	Fruit-Vegetable allergen panel	1	RLA220.10	Fruit-Vegetable allergen panel	10
RLA221	Grain, Flour & Nut allergen panel	1	RLA221.10	Grain, Flour & Nut allergen panel	10
RLA222	Inhalation Asian allergen panel	1	RLA222.10	Inhalation Asian allergen panel	10
RLA223	Food Asia allergen panel	1	RLA223.10	Food Asia allergen panel	10
RLA5-CSU	s-BHRA (HR-Urticaria Test kit)	1			
RLA800	Customer Designed panel variant *	1	RLA800.10	Customer Designed panel variant *	10
*) List of available allergens for panel variants:					

### RefLab ApS

*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 Bureau Veritas. All supporting documentation is retained at the premises of the manufacturer.*

*This declaration of conformity represents products placed on the market before 26-May-2022. The update is solely due to changes in personnel and responsibilities in the organization.*

**Signature:**



**Henrik Christensen**  
Chief Executive Officer

**Place and date (dd-mm-yyyy) of issue:**

Hvidovre, 09-Sep-2024