

17.11.2023

## Annex to the Declaration of Conformity

### To whom it may concern:

Dr. Fooke-Achterrath Laboratorien GmbH, Habichtweg 16, 41468 Neuss, Germany declares that the following list of allergens is the detailed information of the Product Name "Allergen-coupled Discs (Single Allergen, Allergen Mixes)" with the Product Number "Allergen Code", mentioned in the Declaration of Conformity.

Item code	Description
c 00068	Articaine
c 00082	Lidocaine
c 00088	Mepivacaine
c 00196	Epinephrine
c 00108	Ciprofloxacin
c 00125	Dexametazone
c 00056	Amoxiciline
c 00055	Cephalosporin
c 00153	Metronidazol
c 00089	Bupivacain
c 00172	Ketoprofen
c 00194	Azithromycin
c 00170	Clarithromycin
c 00083	Procain
c 00210	Tetracain

Sincerely,

  
**DR FOOKE**  
LABORATORIEN GMBH  
Habichtweg 16 41468 Neuss  
Tel: (0 21 31) 29 84 - 0 · Fax: (0 21 31) 29 84 - 184

Dr. Margrit Fooke-Achterrath  
General Manager

## EC-Declaration of Conformity

For the purpose of 98/79/EC Directive on *in vitro* diagnostic medical devices

Product Name: **Allergene-coupled Discs (Single Allergens, Allergen Mixes)**  
Product Number: **Allergene Code**

The product is designed and manufactured for the purpose of 98/79/EC Directive on *in vitro* diagnostic medical devices in the sole responsibility of:

**DR. FOOKE-ACHTERRATH Laboratorien GmbH**  
Habichtweg 16  
D-41468 Neuss  
Germany

The product meets all applicable requirements of Directive 98/79/EC.  
The conformity assessment procedure followed Directive 98/79/EC Annex III.

This declaration is valid until 25<sup>th</sup> May 2027.

Neuss, 18<sup>th</sup> May 2022

**DR. FOOKE-ACHTERRATH Laboratorien GmbH**



Dr. Margrit Fooke-Achterrath  
- General Manager -