



Declaration of Conformity

In accordance with EC Directive 98/79/EC relating to *in vitro* diagnostic medical device, We herewith declare that the under-mentioned device, in view of its design and type of construction, meets the requirements of the above EC Directive.

If the device is modified without the agreement of the undersigned, this declaration becomes invalid.

Description of Device

PROTIA *Allergy-Q* Inhalant Panel
PROTIA *Allergy-Q* Food Panel
PROTIA *Allergy-Q* Atopy Panel
PROTIA *Allergy-Q* 64 Inhalant Panel
PROTIA *Allergy-Q* 64 Food Panel
PROTIA *Allergy-Q* Food A Panel
PROTIA *Allergy-Q* 64S Panel
PROTIA *Allergy-Q* 10A Panel
PROTIA *Allergy-Q* 96M Panel

In vitro diagnostic test for use in the quantitative determination of allergen-specific IgE concentrations in human serum or plasma, using immunoblotting technique

Relevant EC Directives: Directive 98/79/EC

Classification: General IVDs (neither AnnexII, List A+B nor for self-test)

EDMA Code: 12 02 01 06 00 (Immunoglobulin E – Screen)

Harmonized Standards: EN ISO 13485:2012, EN ISO 14971:2012, EN 13612:2002, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 15223-1:2016, ISO 23640:2011, EN 62366:2008

Manufacturer: ProteomeTech Inc.
A-702, 401 Yangcheon-Ro, Gangseo-Gu, Seoul 07528, Korea

Authorized Representative: MT Promedt Consulting GmbH
Altenhofstrasse 80, 66386 St. Ingbert, Germany

Date: May 24, 2018

Signature (CEO, Kook Jin Lim):

