ThermoFisher SCIENTIFIC

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EC DECLARATION OF CONFORMITY

Ref. No: DC Specific IgE/06

Phadia AB, Rapsgatan 7P, P.O. Box 6460, 751 37 Uppsala, Sweden

hereby declare that the products listed below fulfil the requirements in the "Directive 98/79/EC of the European parliament and of the council of 27 October 1998 on *in vitro* diagnostic medical devices" (IVDD), the Swedish Medical Devices Act (1993:584) and the regulation LVFS 2001:7. The products are classified as "General devices" (all devices other than those covered by IVDD Annex II and self-testing devices). Conformity assessment is performed according to IVDD Annex III.

Art. No.	Product Name
10-9253-01	ImmunoCAP Specific IgE
10-9253-03	ImmunoCAP Specific IgE
10-9254-01	ImmunoCAP Specific IgE Calibrators
10-9256-01	ImmunoCAP IgE/ECP/Tryptase Sample Diluent
10-9310-01	ImmunoCAP Specific IgE Conjugate 400
10-9310-03	ImmunoCAP Specific IgE Conjugate 400
10-9312-01	ImmunoCAP Specific IgE Curve Control Strip
10-9316-01	ImmunoCAP Specific IgE Conjugate 100
10-9360-01	ImmunoCAP IgE/ECP/Tryptase Sample Diluent
10-9386-01	ImmunoCAP Specific IgE Calibrator Strip
10-9408-01	ImmunoCAP Specific IgE Curve Controls
10-9419-01	ImmunoCAP Specific IgE Conjugate
10-9419-03	ImmunoCAP Specific IgE Conjugate
10-9445-01	ImmunoCAP Specific IgE Negative Control
10-9445-03	ImmunoCAP Specific IgE Negative Control
10-9449-01	ImmunoCAP Specific IgE Control
10-9450-01	ImmunoCAP Specific IgE f1Control
10-9459-01	ImmunoCAP Specific IgE Calibrator Strip 0-100
10-9460-01	ImmunoCAP Specific IgE Calibrators 0-100
10-9462-01	ImmunoCAP Specific IgE 0-100
10-9462-03	ImmunoCAP Specific IgE 0-100
10-9463-01	ImmunoCAP Specific IgE Conjugate 0-100
10-9528-01	ImmunoCAP Specific IgE Control L
10-9528-03	ImmunoCAP Specific IgE Control L
10-9529-01	ImmunoCAP Specific IgE Control M
10-9529-03	ImmunoCAP Specific IgE Control M

2012-11-13
Date

Jenny Nystrand
Jenny Nystrand, Regulatory Manager,
Global Market Access

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Ref. No: DC Specific IgE/06

10-9530-01 ImmunoCAP Specific IgE Control H
10-9530-03 ImmunoCAP Specific IgE Control H
14-4417-01 ImmunoCAP Specific IgE Anti-IgE

END OF LIST