



NOFER INSTITUTE OF OCCUPATIONAL MEDICINE

RESEARCH LABORATORY OF MEDICINE AND
VETERINARY PRODUCTS IN THE GMP QUALITY SYSTEM

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CERTIFICATE OF SENSITIZATION TEST

Filtering half masks:

XF 110V FFP1 NR D

produced in accordance with the technical documentation no. DTCE/AP/003/2012

Respirators class FFP1 are designed to protect respiratory system against harmful effect of dusts, solid and liquid aerosols, where Occupational Exposure Limit (OEL) is higher or equal to 2 mg/m³, provided that the concentration of dispersed phase of aerosol should not exceed 4x OEL.

Filtering half masks:

XF 210V FFP2 NR D

produced in accordance with the technical documentation no. DTCE/AP/002/2012

Respirators class FFP2 are designed to protect respiratory system against harmful effect of dusts, solid and liquid aerosols, where Occupational Exposure Limit (OEL) is higher than 0.05 mg/m³, provided that the concentration of dispersed phase of aerosol should not exceed 10x OEL.

Filtering half masks:

XF 310V FFP3 NR D

produced in accordance with the technical documentation no. DTCE/AP/001/2012

Respirators class FFP3 are designed to protect respiratory system against harmful effect of dusts, solid and liquid aerosols, where Occupational Exposure Limit (OEL) is lower or equal to 0.05 mg/m³, provided that the concentration of dispersed phase of aerosol should not exceed 30x OEL.

**CERTIFICATE PREPARED UNDER REPORT NO. NLABLEK 518/2012
CONTAINING 38 PAGES**

PERFORMED ACCORDING TO OECD TG GUIDELINES METHOD NO. 406 "SKIN SENSITIZATION" 1992 B.6 ACUTE TOXICITY PROCEDURE - SKIN SENSITIZATION. DZ. U. RP, ANNEX NO. 232, POS. 2343 OF 31 DECEMBER 2003, 24 OCTOBER 2004 AND 26 JULY 2006 AND PN-EN ISO 10993-10: 2011 STANDARD "BIOLOGICAL EVALUATION OF MEDICAL DEVICES -PART 10: TESTS FOR IRRITATION AND SKIN SENSITIZATION"

WITH THE APPROVAL OF THE LOCAL ETHICAL COMMITTEE NO. 9 FOR THE EXPERIMENTS ON ANIMALS IN LODZ, 72/LB RESOLUTION NO. 498/2009 OF 25 JANUARY 2010

Lodz, 26th October 2012

