

MANUFACTURER: **Vitrotest Europe Sp. z O.O.**

ADDRESS: **Krakowska str., 139-155, 50-428, Wroclaw, Poland**

PRODUCT NAME: **Vitrotest Ascaris lumbricoides IgG**
ELISA test kit for the detection of IgG class antibodies to
Ascaris lumbricoides

PRODUCT CATALOGUE NUMBER: **EL051-96**

GMDN CODE: **52133**

We hereby declare that the above mentioned product meet the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

CLASSIFICATION: In vitro medical device, other device (not applicable to list A or B of Annex II of Directive 98/79/EC, not a product for self-testing, not for performance evaluation).

CONFORMITY ROUTE: Annex III of Directive 98/79/EC.

APPLICABLE STANDARDS: EN ISO 13485:2016; EN ISO 18113-1:2011;
EN ISO 14971:2019; EN ISO 18113-2:2011;
EN 13612:2002; EN ISO 23640:2015.
EN ISO 15223-1:2016;

This Declaration of conformity is issued under the responsibility of the manufacturer.

Edition 1

Wroclaw, Poland

15.02.2022

Issued in

Date

Vitrotest Europe Sp. z o.o.
ul. Krakowska 139-155, 50-428 Wroclaw
NIP: 8992881308, REGON: 386329301
KRS: 0000844411



Galyna Rayevska, Ph.D.
Chief of the Board

MANUFACTURER: **Vitrotest Europe Sp. z O.O.**

ADDRESS: **Krakowska str., 139-155, 50-428, Wroclaw, Poland**

PRODUCT NAME: **Vitrotest Toxocara canis IgG**
ELISA test kit for the detection of IgG class antibodies to
Toxocara canis

PRODUCT CATALOGUE NUMBER: **EL058-96**

GMDN CODE: **52418**

We hereby declare that the above mentioned product meet the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

CLASSIFICATION: In vitro medical device, other device (not applicable to list A or B of Annex II of Directive 98/79/EC, not a product for self-testing, not for performance evaluation).

CONFORMITY ROUTE: Annex III of Directive 98/79/EC.

APPLICABLE STANDARDS: EN ISO 13485:2016; EN ISO 14971:2019; EN 13612:2002; EN ISO 15223-1:2016; EN ISO 18113-1:2011; EN ISO 18113-2:2011; EN ISO 23640:2015.

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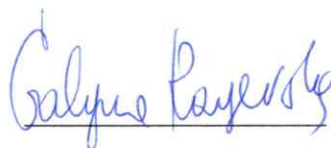
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