

Certificate of Approval

This is to certify that the Management System of:
PZ CORMAY Spółka Akcyjna
ul. Wiosenna 22, 05-092 Łomianki, Poland

has been approved by LRQA to the following standards:

ISO 9001:2015
EN ISO 13485:2016



P.G. Cornelissen - Area Manager North Europe

Issued by: Lloyd's Register (Polska) sp. z o.o.

for and on behalf of: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current issue date: 25 January 2019
Expiry date: 16 August 2021
Certificate identity number: 10168229

Original approval(s):
ISO 9001 – 16 January 1998
ISO 13485 – 17 August 2009

Approval number(s): ISO 9001 – 0053000 | ISO 13485 – 0053001

The scope of this approval is applicable to:
ISO 9001:2015

Design, production and distribution of in vitro diagnostic reagents for in vitro diagnostics for medical, industrial and scientific laboratories and design, production, sales and maintenance of in vitro diagnostic medical devices.

EN ISO 13485:2016

Design, production and distribution of in vitro diagnostic reagents for in vitro diagnostics for medical, industrial and scientific laboratories and design, production, sales and maintenance of in vitro diagnostic medical devices.



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Certificate Schedule

Certificate identity number: 10168229

Location	Activities
ul. Wiosenna 22, 05-092 Łomianki, Poland	ISO 9001:2015 EN ISO 13485:2016 Registration address.
Orphée S.A. chemin du Champ-des-Filles 19, 1228 Plan-Les-Ouates Geneva, Switzerland	ISO 9001:2015 EN ISO 13485:2016 Production and distribution of in vitro diagnostic reagents for in vitro diagnostics for medical, industrial and scientific laboratories and sales and maintenance of in vitro diagnostic medical devices.
Marynin 61 A, 21-030 Motycz, Poland	ISO 9001:2015 EN ISO 13485:2016 Manufacturing of in vitro diagnostic reagents for medical, industrial and scientific
ul. Puławska 303, 02-785 Warszawa, Poland	ISO 9001:2015 EN ISO 13485:2016 Distribution of in vitro diagnostic reagents for medical, industrial and scientific laboratories. Sale and service of medical equipment.
ul. Rapackiego 19A, 19B, 20-150 Lublin, Poland	ISO 9001:2015 EN ISO 13485:2016 Design, production and distribution of reagents of in vitro diagnostics for medical, industrial and scientific laboratories and design, production, sales and maintenance of in vitro diagnostic medical devices.



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