

Current issue date:
Expiry date:
Certificate identity number:

17 August 2021 16 August 2024 10370649 Original approval(s): ISO 13485 - 17 August 2009 ISO 9001 - 16 January 1998

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 Lloyd's Register to the following standards:

ISO 13485:2016, ISO 9001:2015

Approval number(s): ISO 13485 - 0053001, ISO 9001 - 0053000

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.

The scope of this approval is applicable to:

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.

Paul Graaf Chief Operating Officer, Management Systems, MSIS Issued by: Lloyd's Register Quality Assurance Limited



Lloyd's Register Group Limited, its affiliates and subsidiaries, including Lloyd's Register Quality Assurance Limited (LRQA), and their respective officers, employees or agents are, individually and collectively, referred to in this clause as 'Lloyd's Register'. Lloyd's Register assumes no responsibility and shall not be liable to any person for any loss, damage or expense caused by reliance on the information or advice in this document or howsoever provided, unless that person has signed a contract with the relevant Lloyd's Register entity for the provision of this information or advice and in that case any responsibility is exclusively on the terms and conditions set out in that contract. Issued by: Lloyd's Register Quality Assurance Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom



Certificate Schedule

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



Lloyd's Register Group Limited, its affiliates and subsidiaries, including Lloyd's Register Quality Assurance Limited (LRQA), and their respective officers, employees or agents are, individually and collectively, referred to in this clause as 'Lloyd's Register'. Lloyd's Register assumes no responsibility and shall not be liable to any person for any loss, damage or expense caused by reliance on the information or advice in this document or howsoever provided, unless that person has signed a contract with the relevant Lloyd's Register entity for the provision of this information or advice and in that case any responsibility or liability is exclusively on the terms and conditions set out in that contract. Issued by: Lloyd's Register Quality Assurance Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom

JKA ANAGEM SYSTEM 0001