No.18 Qixing Road, Majiadian Town, 443200 Zhijiang City,

Hubei Province, P.R.C

Tel: 86 717 4211111

Fax: 86 717 4225499



Declaration of Conformity

Manufacturer: Allmed Medical Products Co., Ltd

Address: No.18 Qixing Road, Majiadian Town, 443200Zhijiang City, Hubei province,

PEOPLE' S REPUBLIC OF CHINA

SRN: CN-MF-000007970

European Representative: Shanghai International Holding Corp. GmbH(Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Product Code: please refer to the attached confirmation of identical build list as following page

Product Name/Product Classification/Rule/EMDN Code /Basic UDI-DI

EMDN Code	Product Name	Basic UDI-DI	Rule	Classification
M0403	Eye Pads	69415580eyepadX7	4	I

Conformity Assessment Route: Annex II+Annex III of Regulation (EU) 2017/745

We herewith declare in our own responsibility that the above mentioned products meet the Regulation (EU) 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

Regulation and standard

Medical Device Regulation: The object of the declaration described above is in conformity with

Regulation (EU) 2017/745

Common specifications: Not Applicable

Standard Applied: all applicable harmonised standard (published in the official journal of the

European Communities)

ISO 13485:2016 Certificate: Q5 002037 0008 Rev. 04

Expire date of the Certificate: 2025-08-31

Place, Date of Issue: Hubei province, P.R.C,2022-12-28

Signature: Vice General Manager of Quality

Name: Position:

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Confirmation of Identical Build

We, Allmed Medical Products Co., Ltd, No. 18 Qixing Road, Majiadian Town, 443200 Zhijiang City, Hubei province, Peoples Republic of China, as legal manufacturer of the product group Pro-ophta Eye Pads, hereby confirm that the following medical devices are identical in composition and manufacture and are subject to the same quality controls.

Product Number Legal Manufacturer		New Product Number Lohmann & Rauscher	Old Product Number Lohmann & Rauscher
C42100-0012	=	142020	13019
C03902-0007	=	142021	13020
C03902-0008	=	142022	13021
C42100-0013	=	142023	17590
C42100-0014	=	142024	17591
C42100-0015	=	142025	36195

Simon 2023.3.2