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Attestation
of Conformity

No.ICR Polska/P(03)B082

CE

Name and address:	Zhangpu Jiande Medical Equipment Co., Ltd.
of Registered Manufacturer:	Xiatankou,Sui'an Industrial Development Zone Zhangpu,Zhangzhou,Fujian Province,China
Product name:	Disposable Mask
Product type/model:	JDM-001 002 003 004

This Attestation confirms that the product meets the requirements of the following normative documents and within limits of its documents gives presumption of conformity with essential requirements of Directive Regulation (EU) 2016/425.

Relevant EC Directive:	Personal protective equipment (EU) 2016/425
Conformity assessment procedure:	EC Declaration of Conformity (Annex VI of Directive (EU) 2016/425)
Classification:	Class I according Rule 1 of Annex IX of Directive (EU) 2016/425
Applied normative documents:	EN 149:2001+A1:2009

This Attestation of Conformity will remain valid only if Quality Management System Crtificate remains valid and the surveillance audits are conducted.
The assessment process has been carried out in accordance with the program PC-P-07-07.
Evaluation has been carried out in accordance with test reports made by Shanghai MICEZ Equipment Testing & Technical Co., LTD Laboratory.

No. of test report:	JAT-20(03)B082-PPE
Issue date:	20.03.2020
Expiration date:	19.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-1019.

This Attestation applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.

Director:Rafat Kalinowski

Warsaw,20.03.2020.

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Attestation of Conformity

No.ICR Polska/(03)B073

CE

Name and address:	Zhangpu Jiande Medical Equipment Co.Ltd.
of Registered Manufacturer:	Xiatankou,Sui'an Industrial Development Zone Zhangpu,Zhangzhou,Fujian Province,China
Product name:	Disposable Medical Mask
Product type/model:	JDY-001 002 003 004

This Attestation confirms that the product meets the requirements of the following normative documents and within limits of its documents gives presumption of conformity with essential requirements of Directive 93/42/EEC.

Relevant EC Directive:	Medical Device Directive 93/42/EEC
Conformity assessment procedure:	EC Declaration of Conformity (Annex VI of Directive 93/42/EEC)
Classification:	Class I according Rule 1 of Annex IX of Directive 93/42/EEC
Applied normative documents:	EN 14683:2019
Applied Quality Management System:	EN ISO 13485:2016

This Attestation of Conformity will remain valid only if Quality Management System Crtificate remains valid and the surveillance audits are conducted.
The assessment process has been carried out in accordance with the program PC-P-07-07.
Evaluation has been carried out in accordance with test reports made by Shanghai MICEZ Equipment Testing & Technical Co., LTD Laboratory.

No. of test report:	JAT-20(03)B073-MDD
Issue date:	20.03.2020
Expiration date:	19.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-1019.

This Attestation applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.

Director:Rafat Kalinowski

Warsaw,20.03.2020.

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