International Certification Registrar International Certification Registrar

Attestation of Conformity

No. ICR Polska/M6104520

CE

Name and address of Registered Manufacturer:	Medical Supplies Co., Ltd. Industry zone
Product name:	Disposable surgical mask
Product type/model:	DSM-C、DSM-Z

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 VII 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 Certificate 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:	EQT20(03)3101002-MDD
Issue date:	11.03.2020
Expiration date:	10.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-1045.

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: Rafał Kalinowski

Warsaw, 11. 03. 2020.

ICR Polska Co. Ltd.
ul. Plac Przymierza 6, 03-944 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrqa.com

International Certification Registrar

Attestation of Conformity

No. ICR Polska/M8900820

CE

Name and address of Registered Manufacturer:	Medical Supplies Co.,Ltd Industry zone
Product name:	Medical Disposable Coverall
Product type/model:	DC-L

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 VII of Directive 93/42/EEC)
Classification:	Class I according Rule 1 of Annex IX of Directive 93/42/EEC
Applied normative documents:	EN 13795-1-2019
Applied Quality Management System	EN ISO 13485:2016

This Attestation of Conformity will remain valid only if Quality Management System Certificate 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 European Quality Test Co., LTD.

No. of test report:	EQT-2003-031472A-MDD
Issue date:	24.03.2020
Expiration date:	23.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-8908.

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

INTERNATIONAL CERTIFICATION REGISTAR ★ ICR ★ JEDNOSTKA NOTYFIKOWANA Nr 2703 REGISTERED FIRM

Director: Rafał Kalinowski

Warsaw, 24. 03. 2020.

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International Certification Registrar International Certification Registrar

Attestation of Conformity

No. ICR Polska/M6106820

CE

Name and address of Registered Manufacturer:	Medical Supplies Co., Industry zone
Product name:	Isolation gown
Product type/model:	IG-L,IG-F

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 VII of Directive 93/42/EEC)
Classification:	Class I according Rule 1 of Annex IX of Directive 93/42/EEC
Applied normative documents:	EN 14126:2003
Applied Quality Management System	EN ISO 13485:2016

This Attestation of Conformity will remain valid only if Quality Management System Certificate 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:	QET-20(03)3101001-MDD
Issue date:	11.03.2020
Expiration date:	10.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-1068.

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: Rafał Kalinowski

Warsaw, 11. 03. 2020.

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