

Certificate of CE-Registration



Medical Device Safety Service

This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:


Fazo-Luxe LLC
21, Okhangrabo street, 'Gulistan' community
Tashkent district, Tashkent region
111103 Republic of UZBEKISTAN

as stipulated and demanded by the aforementioned Directive. The German Competent Authority has allocated the medical devices of the Manufacturer registration numbers as foreseen in:

Annex A dated September 08, 2020

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the medical devices fulfill the applicable requirements of Directive 93/42/EEC. In compliance with German law, a safety officer has been appointed for Germany.

2020-09-08


Dr. Philipp Hohenbrink
Senior Consultant
MDSS GmbH



Medical Device Safety Service 



MDSS · Schiffgraben 41 · 30175 Hannover, Germany

Fazo-Luxe LLC
Mr. Ruslan Vildanov
21, Okhangrabo street, 'Gulistan' community
Tashkent district, Tashkent region
111103 Republic of UZBEKISTAN
UZBEKISTAN

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30175 Hannover, Germany

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2020.09.08

Updated MDSS Certificate of CE Registration

Dear Mr. Vildanov,

It is our pleasure to enclose the new Certificate of CE-Registration for your products, taking into consideration the recent changes to your range of products.

Please note that registration was performed under § 25 MPG (Medizinproduktegesetz). This is the *Federal Republic of Germany's national interpretation of Medical Device Directive 93/42/EEC*. Registration is therefore in accordance with EU legislation. We remind you that all products must meet the applicable provision of the European and national regulation before they may be placed on the market.

We are looking forward to continuing our good business relationship and wish you a successful product launch in Europe.

Best regards,

Kristina Geringer
Account Administrator
Medical Device Safety Service GmbH

Encl.

1 Certificate of CE-Registration
1 Annex A

MDSS · Medical Device Safety Service GmbH

Handelsregister Hannover HRB 57318 · USt-IdNr. DE 177346163 · Geschäftsführer: Ludger Möller

Bankverbindungen

Sparkasse Hannover

S.W.I.F.T.: SPKHDE2H

IBAN: DE24 2505 0180 0910 0792 77

Commerzbank AG, Hannover

S.W.I.F.T.: COBADEFF 250

IBAN: DE67 2504 0066 0338 8816 00



Annex A dated September 08, 2020
Manufacturer: Fazo-Luxe LLC

UMDNS Code Description Notified Medical Device Product Name & Catalogue Number	UMDNS Code	Risk Class	Cat. Code	Registration Number	NB No. / NB Certificate No.	NB Cert. Valid Until YYYY-MM-DD
Bandages, Plain Gauze	10-281	I	10	DE/CA09/0170/F09/001-01	N.A.	N.A.
Medical gauze bandage non-sterile; Medical woven bandage non-sterile; Medical knitted bandage non-sterile; Medical bleached cloth gauze						
Medical gauze bandage non-sterile: (5m x 7cm), (5m x 10cm), (7m x 10cm), (7m x 12cm), (7m x 14cm)						
Medical woven bandage non-sterile: (3m x 10cm), (3m x 12cm), (3m x 14cm)						
Medical knitted bandage non-sterile: (3m x 10cm), (3m x 12cm), (3m x 14cm)						
Medical bleached cloth gauze: (1m x 84cm), (2m x 84cm), (3m x 84cm), (5m x 84cm), (10m x 84cm)						
Cotton Rolls	13-414	I	10	DE/CA09/0170/F09/002-01	N.A.	N.A.
Hygienic medical hygroscopic cotton wool non-sterile						
Hygienic medical hygroscopic cotton wool non-sterile: 25g, 50g, 100g, 250g						
Surgical/medical face mask, single-use	GMDN 35177	I	10	DE/CA09/0170/F09/003	N.A.	N.A.
Single use medical face mask, three-layer, non-woven						
Single use medical face mask, three-layer, non-woven						

CC

