Safeguarding public health

MHRA

Our Ref: CA 010308

- 2 APR 2008

Benny Arazy
Medes Ltd
5 Beaumont Gate
Shenley Hill
Radlett
Herts
WD7 7AR
United Kingdom

01 April 2008

Dear Benny Arazy,

MEDICAL DEVICES REGULATIONS 2002: REGULATION 19
Registration of Persons Placing General Medical Devices on the Market

Thank you for informing the Competent Authority of the details of ***Manufacturers*** **Name:- Cilita Ltd** located at **Manufacturers Address:- 61 Oktyabrskaya St Ryazan Russia 390010** for whom you are acting as the authorised representative and for supplying the medical device information.

Your registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of "medical device", and that you have classified it/them as falling within Regulation 19 taking into account the intended purpose(s) and mode(s) of action. In accepting your registration, I should make clear that the Competent Authority does not examine each individual notification and therefore cannot and does not necessarily endorse these determinations. Neither does this letter represent any form of accreditation or approval by the UK Competent Authority.

Your registration is based upon your declaration on the RG2 form and means that:

For Manufacturers of Class I medical devices, Assemblers, and Sterilisers

You should now be operating under the Medical Devices Directive and the above Regulations for the products you asked us to register, by fully complying with the essential requirements, CE marking those products or labelling them as such.

For Manufacturers of Custom-made devices

You should be ready to claim compliance with the Directive and Regulations and should be manufacturing custom-made devices in accordance with their requirements.

If you stop placing devices on the market or if you are not complying with the Regulations you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market CE marked devices that do not comply with the regulations.

The information you provided has been recorded against the reference number shown at the top of this letter, which we ask you to quote in all future correspondence and communications.

Please inform us of any changes to:

- the company information
- additional generic groups of devices (not individual products within an existing generic group)
- discontinuation of a generic group of devices.

"LENSES GRUP" SRL

Please use RG2, the Registration form, to tell us about any of these changes.

Thank you for registering the following generic groups of devices:

Class I Devices:
Surgical Instruments (Re-Usable And Non-Powered)
Surgical Instrument Accessories

Custom Made Devices:
None

Products Covered By Article 12:
None

Should you have any queries regarding your registration please do not hesitate in contacting us.

Yours sincerely

Marion Jordis

Regulatory Affairs Administrator

Tel: 020 7084 3101

Fax: 020 7084 3107

Email: marion.jordis@mhra.gsi.gov.uk

MEDES limited
AUTHORIZED REPRESENTATIVE

CERTIFICATE OF CONFORMANCE

Acting as Regulatory Authorized Representative in Europe for **Cilita Ltd.** from **Russia**, we hereby declare that:

The following products listed hereunder or in the "Products Schedule" has been registered with the European Competent authority in the UK (MHRA) on 1 April 2008 Ref. no. CA01308 as Class I..

By submitting the information to the MHRA, the legal requirements for registration have been met. **Cilita ltd**. complies with the requirements of the Medical Device Directive 93/42 EEC amended by 2007/47 and the above products can be CE marked according to the above directive.

Product Schedule

Sr. No.	Product Name / Family
1	Surgical Instruments
2	Surgical Instrument Accessories

For Medes Ltd.

Benny Arazy
General Manager
Medes Ltd.

CE

Date: 07.10.10

"LENSES GRUP" S.R.L.

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E-mail: medes@arazygroup.com WWW.MEDESEUROPE.COM

CERTIFICATE

No. 70565

LL-C Certification

This is to certify that the Quality Management System of Medical Devices of

CILITA

Cilita LLC
Moskovskoye Shosse, bld. 20, office 702
390044 Ryazan
Russia

including workshop:
Stankozavodskaya Str., 7 bld. 45, 390042 Ryazan, Russia

has been assessed and found to be in compliance with the standard

ISO 13485:2016

applicable to

Manufacturing, quality control, packaging, storage and distribution of non-active(non-implantable) medical devices: microsurgical and surgical instruments, including ophthalmic instruments

The certificate has been issued under No. **70565** for the registration period from 18th December 2018 to 27th November 2020. The first certificate date of issue is 28th November 2017.

Approved by

Printed by

S 3137

validity code: **9D9C66B2-B07**
Check the validity of this certificate using this code at **www.ll-c.info**

LL-C (Certification) Czech Republic a.s. | Pobřežní 620/3, 186 00 Praha 8