EC CERTIFICATE

PRODUCTION QUALITY ASSURANCE SYSTEM CERTIFICATE

Cert no. SC0557-15

issued to

Medifactia AB

Lumaparksvägen 7, 12031 STOCKHOLM, SWEDEN

We hereby certify that the Quality System of Medifactia AB for production, final inspection and marketing of

Transit-pellets for evaluation of colon transit,

medical devices in class IIa has been assessed with respect to the conformity assessment procedure according to Annex V of Council Directive 93/42/EEC on Medical Devices, as latest amended by Council Directive 2007/47/EC is implemented in Swedish Law by the national regulation LVFS 2003:11, and found to comply with the requirements

This certificate applies to activities performed at

Ljusslingan 4, floor 8, SE-120 31 Stockholm, Sweden

Originally issued	2016-05-17
Decision date	2020-04-29
Expiry date	2024-05-26

Issued by Notified body 0402

Signed by: Helén Dahl
I am the author of this document
2020-04-29 10:24:32 +01:00

Helén Dahl

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Ackred. no 1002
Certification of Management Systems
ISO/IEC 17021-1

Conditions

Validity

The certificate will remain valid until the expiry date, and allows the holder to use RISE notified body identification number 0402 in conjunction with the CE-mark, on products covered by this certificate, provided that the conditions stated below are fulfilled:

- that surveillance audits are performed, with approved result;
- that the company notifies RISE on all modifications on the products, and that the company does not apply the CE-mark to any new or modified products without confirmation from RISE;
- that the company notifies RISE on all significant changes in the quality system, in its activities and/or organization;
- that the certificate is not used in a misleading manner, e.g. in marketing activities;
- that the company notifies RISE about vigilance actions, if any.

Basis for certificate

- The documentation presented has been examined and assessed by RISE in accordance with LVFS 2003:11, Annex V.
- An initial audit and follow-up audits of the quality system at the company's premises in Stockholm has been performed by RISE.
- RISE file Ecert ID 67638

Surveillance

RISE will perform surveillance inspections to ensure that the company maintains and applies the quality system that is subject of the certificate.

In accordance with the EU Commission recommendations of 2013-09-24, there will also be unannounced audits once per every three years. These audits can be performed at the manufacturers as well as at selected crucial supplier's premises.

Miscellaneous

Additional conditions appear in "RISE General Terms – Assignment" and "Rules and process assessment of medical devices as notified body LVFS 2003:11".

Certificate history

Issue	Date	Activity
1	17th May 2016	Original certificate
2	11th December	Certificate revised, new adress
3	9th November 2018	Certificate revised, new adress
4	29th April 2020	Certificate revised, validity extended.

Register of products covered by the certificate

Product	Art.no.	Class
Transit-Pellets	0 7350099 55000 3	IIa

Note: New products in **bold**