3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
Notified Body No. 2265

EC CERTIFICATE

No. 2019-MDD/QS-076/A

issued in compliance with the Council Directive 93/42/EEC as amended,
certifies that the medical device of Class IIa,

Degasin®
Simethicone 280 mg
(16, 32 soft capsules)

Alternative Brand Names: Degasil®, Degasin® Intens, Simeticon AL 280 mg Weichkapseln, Simeticon STADA® 280 mg Weichkapseln, Healthypharm Simeticon Intens 280 mg, Etos Simeticon Intens 280 mg, Kruidvat Simeticon Intens 280 mg

manufactured by company

WALMARK, a.s.
Oldřichovice 44, 739 61 Třinec, Czech Republic

is manufactured under conditions fulfilling the quality system requirements of Annex II, excluding (4), of the Directive 93/42/EEC as amended.

The Notified Body No. 2265 has performed an audit of the above device quality system. The full quality assurance system has been assessed and found that it meets the requirements above. The quality system is subject to continuous surveillance according to Annex II, Sections 3.3, and 5, of the Directive 93/42/EEC as amended. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Reports No. 310446, ICT_111 and the Final protocols No. 310446/2019, 310446A/2021.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of the above referenced model of medical device and it does not substitute the design or type-examination procedures, if such is required. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26th, 2024 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfilment of relevant legal and other requirements by manufacturer.

Notified body · 3EC international · NB 2265 · NOTIFIKOVANÁ OSOBA

Dr. Katarína Tomin Srdošová
Responsible to act on behalf of NB 2265

At Bratislava, on March 26th, 2021
Version A) supersedes the EC Certificate No. 2019-MDD/QS-076 issued on November 25th, 2019

Certificate history:

Revision	Date of issue	Application for Conformity Assessment of MD number	Description
0	November 25th, 2019	310446	Recertification
A	March 26th, 2021	310446A	The new brand adding