CERTIFICATE OF ANALYSIS

Product name: **Degasin 280 mg**
SAP code: 16-07528
Specification: SV/KJ/0221
Quantity: 7.040 pcs.
Batch number: D1L3298

Expiration date: 30.09.2025
Manufacturing date: 07.10.2021

Parameters /attributes/	Limits (lower-upper)	Result	Unit
Characteristics	orange opaque soft gelatine capsules, Oval 6	complies	-
The average fill weight	266-294	280	mg
The average capsule weight	378 – 462	420	mg
Uniformity of mass fillings	min. 18 caps. ± 10% max 2 caps. ± 20% from the observed average weight	complies	- -
Disintegration	max. 30	7	min
Identity of titanium dioxide, (E171, CI 77891)	complies	complies	-
Identity of dye Yellow No.6, (E110, CI 15985)	complies	complies	-
Identity of Carmoisine, (E122, CI 14720)	complies	complies	-
Identity of polydimethylsiloxan	complies	complies	-
Content of polydimethylsiloxan	240,0 – 290,0	256.0	mg/cps
TAMC*	max. 1 000	complies	CFU/g
TYMC**	max. 100	complies	CFU/g
Escherichia coli	negative/g	complies	-
Package	complies	complies	CFU/g
Lot and expiry date		complies	-

*TAMC = Total aerobic microbial count
**TYMC = Total combined yeasts and moulds count

Decision for use: A QV Material meets the specification

Approved by: J. Myslivec
QC manager

WALMARK® a.s.
STADA GROUP
Oldřichovice 44, 739 61 Třinec
IČ: 00536016, DIČ: CZ699003348
skupinová registrace DPH
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Date of approval: 12.01.2022

EC DECLARATION OF CONFORMITY
with regards to Annex II of EU Medical Device Directive 93/42/EEC

This declaration of conformity is issued in accordance with the Article 13 (2) of Act No. 22/1997 Coll., On Technical Requirements for Products, as amended (hereinafter the Act) and in accordance with Council Directive 93/42 / EEC, as amended, the requirements are taken over by Government Decree 54/2015 Coll. as amended, laying down technical requirements for medical devices under the sole responsibility of the below mentioned manufacturer.

Manufacturer: **WALMARK, a.s.**
Oldřichovice 44
739 61 Třinec 1
Czech Republic

Name of medical device: Degasin® Simethicone 280 mg
Product identification number: D1L3298
Expiry date: 2025 09
Pieces: 7.040

Classification of medical device: Class IIa under rule No.5 Annex IX excluding point 4 Council Directive 93/42/EEC

GMDN code: 47579

The object of the declaration described above is in conformity with the relevant Community harmonisation legislation:
Council Directive 93/42/EEC, as amended,
Act No. 268/2014 Coll., as amended.

References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared:
EN ISO 13485:2016
EN ISO 14971:2019
EN ISO 15223-1:2016

Technical documentation is retained by the manufacturer mentioned above.

Notified body number 2265, 3EC International a.s, Hraničná 18, Bratislava 821 05, Slovak Republic performed conformity assessment and issued the certificate:
No. 2019-MDD/QS-076/A

Signed for and on behalf of: .....

WALMARK® a.s.
STADA GROUP
Oldřichovice 44, 739 61 Třinec
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Name, function: Ing. David Görög, Quality Site Head

Place and date of issue: Třinec, Czech Republic 12.01.2022