Dr. Müller
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EC DECLARATION OF CONFORMITY

According to the European Directive 93/42/EEC (consolidated by the Directive 2007/47/EC) concerning medical devices, as amended, Annex II, with the exception of requirements of Annex II, Article 4.

Name and address of the company: **Dr. Müller Pharma s.r.o.**
U Mostku 182
503 41 Hradec Králové
Czech Republic
Ident. No: 63218976 **VAT No: CZ63218976**
Registered by Trade Register OR KS in Hradec Králové, part C, enclosure 7932

SRN: CZ-MF-000000005

Place of Manufacture:

Dr. Müller Pharma s.r.o.
U Mostku 182
503 41 Hradec Králové
Czech Republic

Dr. Müller Pharma s.r.o.
U Mostku 447/7
503 41 Hradec Králové
Czech Republic

We declare as manufacturer under our responsibility that the following medical devices meet the conditions of European Directive 93/42/EEC (consolidated by the Directive 2007/47/EC), Annex II, with exception of requirements of Annex II, Article 4.

Type: **HYALOSAN vaginal suppositories (10 suppositories)**

Risk classification: **IIa** (rule 5 of European Directive 93/42/EEC, annex IX)

GMDN code: **47673**

Applied Standards:

ISO 9001:2015 (czech translate ČSN EN ISO 9001:2016)	Quality management systems – Requirements.
EN ISO 13485:2016 (czech translate ČSN EN ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes.
ČSN EN ISO 14971:2020	Medical devices - Application of risk management to medical devices.
ČSN EN IEC 60812 ed. 2:2019	Analysis techniques for system reliability – Procedure for failure mode and effects analysis (FMEA).
ČSN EN ISO 10993-1:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
ČSN EN ISO 10993-5:2010	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
ČSN EN ISO 10993-10:2014	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
ČSN EN ISO 15223-1:2017	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements.
ČSN EN 1041+A1:2014	Information supplied by the manufacturer of medical devices.
ISO 7000:2019	Graphical symbols for use on equipment — Registered symbols.
ČSN EN ISO 14644-1:2019	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration.

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Česká republika

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OR KS Hradec Králové
oddíl C, vložka 7932

BANKOVNÍ SPOJENÍ:
ČSOB Hradec Králové
č.ú.: 177 124 383/300

tel.: +420 495 809 111
e-mail: info@muller-pharma.cz
www.muller-pharma.cz

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ČSN EN ISO 14644-2:2016	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration.
MEDDEV 2.4/1 rev.9	Guidance document - Classification of Medical Devices
MEDDEV 2.7/1 rev.4	Clinical evaluation: a guide for manufacturers and notified bodies
MEDDEV 2.12/1 rev.8	Guidelines on a Medical Devices Vigilance System
MEDDEV 2.12/2 rev.2	Post Market Clinical Follow-up studies
MDCG 2020-7	Post-market clinical follow-up (PMCF) Plan Template, A guide for manufacturers and notified bodies
MDCG 2020-8	Post-market clinical follow-up (PMCF) Evaluation Report Template, A guide for manufacturers and notified bodies
MDCG 2020-6	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC, A guide for manufacturers and notified bodies

Conformity Assessment Procedure: Medical Device Directive 93/42/EEC (consolidated by the Directive 2007/47/EC), Annex II, with the exception of requirements of Annex II, Article 4.

Intended use:
HYALOSAN vaginal suppositories is medical device intended to keep the natural moisture of vaginal environment. It used to promote of mucosal regeneration and recovery of natural condition of vaginal environment in trouble due to: vaginal dryness associated with hormonal changes in all stages of a woman's life, especially during menopause, postpartum, breastfeeding, chemotherapy and radiotherapy, or gynecologically operations, or atrophy of the vaginal mucosa and epithelium, with itching, burning, redness or unpleasant feelings sexual intercourse.
Hyalosan vaginal suppositories containing hyaluronic acid.
Only for vaginal use.

Any non-authorised variations in the Declaration will result that the Declaration becomes invalid.

Notified body: **3EC International a.s.**
Hraničná 18
821 05 Bratislava
Slovenská republika

Identification No: 2265

Certificate No: **2019-MDD/QS-082**

All batches of medical devices are produced in accordance with the specifications in the technical file documentation (No. 05-00, as amended) and are documented in records of batch production.

Name and address of the person responsible for storage of the technical documentation:
Mgr. Veronika Salfická
Dr. Müller Pharma s.r.o.
U Mostku 182
503 41 Hradec Králové
E-mail: salficka@muller-pharma.cz

In Hradec Králové, 31. 8. 2021

Dr. Müller
PHARMA
U Mostku 182
503 41 Hradec Králové 7
(10)

PharmDr. Kateřina Lohnická
Head of Regulatory Affairs and
Pharmacovigilance Department

Dr. Müller Pharma s.r.o.
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