m.Chisinau; Calea Orheiului 111/5
tel. 406299; fax. 406271
tel.GSM 069140864
orele de lucru: 8.00 – 17.00

г.Кишинэу ; Калеа Орхеюулуй 111/5
тел. 406299; факс. 406271
моб тел, 069140864.
рабочее время: 8.00 – 17.00

Către Agenţia Medicamentului
şi Dispozitivelor Medicale
Secţia management şi supraveghere dispozitive medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. ... . din .....

Solicitantul **ÎM „Becor"SR**, cu sediul **str. Calea Orheiului 111/5. mun. Chişinău,**
(adresa)

tel./fax: 022406290, e-mail v.luca@becor.md
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea şi punerea la dispoziţie pe piaţă a:

Contraceptiv intrauterin „Steriliet Yunona - T"

Producător: **CJSC "Medical enterprise SIMURG", Republica Belorusa** prin distrbuitor: SIA Simurg Balticum, Latvia

Se anexează următoarele acte:
1. Certificatul CE
2. Declaratia de Conformitate
3. ISO
4. Declaraţie pe proprie răspundere
5. Pover of attorney

Data 02.10.2023 Semnătura

Tabelul de recepţionare a notificării
(se completează de către Agenţie în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepţionării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenţie (în cazul acceptării recepţionării)	
Numele, prenumele, funcţia persoanei responsabile de recepţionarea dosarului	
Semnătura persoanei responsabile	

CERTIFICATE

EC No 1434-MDD-562/2019
Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies,
that the quality assurance system in the organization:

Closed Joint Stock Company "Medical enterprise Simurg"
Generala Lyudnikova ave. 13, room 413 Vitebsk Belarus

for the design, manufacture and final inspection of medical device
class II a

Silicone pessaries

complies with requirements

of Annex II, section 4 to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 2019-11-15 to 2024-05-27

The date of issue of the Certificate: 2019-11-15

The date of the first issue of the Certificate:2019-11-15

CE 1434

Application No: 081/2018
Module: H2

mgr Anna Wyroba
Vice-President

ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-282/2021

List of medical devices covered by the certificate:

YUNONA T
YUNONA T Ag
YUNONA MULTI
YUNONA MULTI Ag

CE 1434

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.05.20 15:56:47 +02'00'
Vice-President

Issued under the Contract No. MD-040/2020
Application No: 073/2020
Certificate bears the qualified signature.
Warsaw, 20.05.2021
Module H2

CERTIFICATE

EC Certificate No. 1434-MDD-282/2021

EC Type-examination
Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that manufactured by:

Simurg Balticum Slokas iela 52 lit 6
LV1007 Riga
Latvia

medical devices, class III

YUNONA

The list of medical devices covered by this certificate is provided in the annex 1

were examined in accordance with Annex III to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 24.05.2021 to 27.05.2024

The date of issue of the Certificate: 24.05.2021

The date of the first issue of the Certificate: 24.05.2021

CE 1434

Issued under the Contract No. MD-40/2020
Application No: 073/2020
Certificate bears the qualified signature.
Warsaw, 20.05.2021
Module B1

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.05.20 15:56:14 +02'00'
Vice-President

REPUBLICA MOLDOVA IDNO 1003600060028 «BECOR» S.R.L. CHISINAU

CERTIFICATE

EC Certificate No. 1434-MDD-281/2021
Full Quality Assurance System
Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Simurg Balticum Slokas iela 52 lit 6
LV1007 Riga
Latvia

for the design, manufacture and final inspection of
medical devices, class III

YUNONA

The list of medical devices covered by this certificate is provided in the annex X1to EC Design-examination Certificate No.1434-MDD-282/2021

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 24.05.2021 to 27.05.2024

The date of issue of the Certificate: 24.05.2021

The date of the first issue of the Certificate: 24.05.2021

CE 1434

Issued under the Contract No. MD-40/2020
Application No: 073/2020
Certificate bears the qualified signature.
Warsaw, 20.05.2021
Module H2

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.05.20 16:07:22 +02'00'
Vice-President

SIA Simurg Balticum
4 Dauguļu street, Riga, LV-1002, Latvia
Reg. LV 40203083026
Account No: LV38HABA0551043811323

DECLARATION OF CONFORMITY № 002.04-2020

Technical file IUD 002.04.2020

Product:	**Intrauterine contraceptive device "Yunona T"**
Name of the medical device modifications:	*See Annex A*
MANUFACTURER: **Address:**	**SIA "Simurg Balticum"** 4 Dauguļu street, Rīga, LV-1002, Latvia E-mail: regimants.baranovskis@sterilization-baltics.com Website: www.simurg-balticum.com
Field of application:	Gynecology
Sterilization:	**YES**
Measurement functions:	**NO**
Classification:	**III, rule 13** (Part III. Classification) of Annex IX of Directive 93/42/EEC *(reguła 13, § 4, Rozporządzenie Ministra Zdrowia z dnia 5 listopada 2010 r. w sprawie sposobu klasyfikowania wyrobów medycznych)*
The scheme of conformity assessment procedure:	Annex II of Directive 93/42/EEC (Full quality assurance system)
The list of harmonized standards applied in whole or in the part and other applied standards and requirements	*See Annex B*

Declaration of conformity confirms the fulfillment of fundamental requirements for medical products in accordance with Annex I of Directive 93/42/EEC.
The assessment of conformity is carried out in accordance with Annex II of Directive 93/42/EEC.
The assessment of conformity is carried out with the participation of the Notified Body POLISH CENTER FOR TESTING AND CERTIFICATION S.A. (Notified Body No. 1434).

Certificate:

Date: 29 April, 2022

Chairman of the Board
SIA Simurg Balticum _____ / Regimants Baranovskis /
(signature)

SIA Simurg Balticum
4 Daugulu street, Riga, LV-1002, Latvia
Reg. LV 40203083026
Account No: LV38HABA0551043811323

Annex A

Product:	**Intrauterine contraceptive device "Yunona T"**
Name of the medical device modifications:	*Intrauterine contraceptive device "Yunona T"*
	Intrauterine contraceptive device "Yunona T Ag"
	Intrauterine contraceptive device "Yunona Multi"
	Intrauterine contraceptive device "Yunona Multi Ag"

SIA Simurg Balticum
4 Daugulu street, Riga, LV-1002, Latvia
Reg. LV 40203083026
Account No: LV38HABA0551043811323

Annex B

EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018.

EN ISO 14971:2012 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007- 10-01).

EN 1041:2008 Information supplied by the manufacturer of medical devices.

EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03).

EN ISO 10993-1:2009 Biological evaluation of medical devices. Part 1: Evaluation and test-ng within a risk management process (ISO 10993-1:2009).

EN ISO 10993-3:2014 Biological evaluation of medical devices. Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014).

EN ISO 10993-5:2009 Biological evaluation of medical devices. Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009).

EN ISO 10993-6:2009 Biological evaluation of medical devices. Part 6: Tests for local effects after implantation (ISO 10993-6:2007).

EN ISO 10993-7:2008 Biological evaluation of medical devices. Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008).

EN ISO 10993-11:2009 Biological evaluation of medical devices. Part 11: Tests for systemic toxicity (ISO 10993-11:2006).

EN ISO 10993-12:2012 Biological evaluation of medical devices. Part 12: Sample preparation and reference materials (ISO 10993-12:2006).

EN ISO 11135-1:2007 Sterilization of health care products. Ethylene oxide. Part 1: Requirements for development, validation and routine control of a sterilization process for medical de-vices (ISO 11135-1:2007).

EN ISO 11607-1:2009 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006).

EN ISO 11737-1: 2006 Sterilization of health care products - microbiological methods - Part 1: determination of a population of microorganisms on products (ISO 11737-1: 2006).

EN ISO 11737-2: 2009 Sterilization of medical devices - microbiological methods - Part 2: tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2: 2009).

ISO 7439-2015 Copper-bearing contraceptive intrauterine devices - Requirements and tests.

ISO 10993-10:2010 Biological evaluation of medical devices. Part 10: Tests for irritation and skin sensitization.

ISO 14644-1:2015 Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration.

m.Chisinau; Calea Orheiului 111/5
tel. 406299; fax. 406271
tel.GSM 069140864
orele de lucru: 8.00 – 17.00

г.Кишинэу ; Калеа Орхеюулуй 111/5
тел. 406299; факс. 406271
моб тел, 069140864.
рабочее время: 8.00 – 17.00

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: **ÎM „Becor"SRL**,
cu sediul **str. Calea Orheiului 111/5., mun. Chişinău,**,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele şi datele furnizate pentru notificarea dispozitivului medical:

Contraceptiv intrauterin „Steriliet Yunona - T"

Producător**: : CJSC "Medical enterprise SIMURG", Republica Belorusa** prin distrbuitor: SIA Simurg Balticum, Latvia

Sunt autentice şi corespund realităţii.

Farmacist. Luca Victoria
Numele, prenumele şi funcţia

Semnătura

Data 02.10.2023

REPUBLICA MOLDOVA mun. CHIŞINĂU IDNO 1003600080808 «BECOR» S.R.L. PENTRU CONTRACTE SOCIETATEA CU RĂSPUNDERE LIMITATĂ

BUREAU VERITAS
Certification

EN ISO/IEC 17021-1
S2-424

Certification

Awarded to

SIMURG BALTICUM SIA

SLOKAS 52, LIT6, RĪGA, LV-1007, LATVIA

Bureau Veritas Certification certify that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standard detailed below

STANDARD

ISO 9001:2015

SCOPE OF CERTIFICATION

PRODUCTION, ASSEMBLY, PACKING AND LABELLING OF GENERAL NON - ACTIVE, NON - IMPLANTABLE MEDICAL DEVICES. SUBASSEMBLY, PACKING AND LABELLING GENERAL ACTIVE MEDICAL DEVICES (NON-IMPLANTABLE) AND NON - ACTIVE IMPLANTS.

Original cycle start date:	**07-05-2018**
Expiry date of previous cycle:	**06-05-2021**
Certification/Recertification audit date:	**06-04-2021**
Certification/Recertification cycle start date:	**07-05-2021**
Subject to the continued satisfactory operation of the organisation's Management System, this certificate expires on:	**06-05-2024**

Certificate Number: **LV007287** *Version:* **1** *Revision date:* **05-05-2021**

Certification body address: Bureau Veritas Latvia SIA, Duntes street 17a, Riga, LV-1005, Latvia

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.

To check this certificate validity please call +371 67323246

BUREAU VERITAS
Certification

EN ISO/IEC 17021-1
S2-424

Certification

Awarded to

SIMURG BALTICUM SIA

SLOKAS 52, LIT6, RĪGA, LV-1007, LATVIA

Bureau Veritas Certification certify that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standard detailed below

STANDARD

ISO 13485:2016

SCOPE OF CERTIFICATION

PRODUCTION, ASSEMBLY, PACKING AND LABELLING OF GENERAL NON - ACTIVE, NON - IMPLANTABLE MEDICAL DEVICES. SUBASSEMBLY, PACKING AND LABELLING GENERAL ACTIVE MEDICAL DEVICES (NON-IMPLANTABLE) AND NON - ACTIVE IMPLANTS.

Original cycle start date:	**07-05-2018**
Expiry date of previous cycle:	**06-05-2021**
Certification/Recertification audit date:	**06-04-2021**
Certification/Recertification cycle start date:	**07-05-2021**
Subject to the continued satisfactory operation of the organisation's Management System, this certificate expires on:	**06-05-2024**

Certificate Number: **LV007288** *Version:* **1** *Revision date:* **05-05-2021**

BUREAU VERITAS

Security address: Bureau Veritas Latvia SIA, Duntes street 17a, Riga, LV-1005, Latvia

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.

To check this certificate validity please call +371 67323246

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Contraceptiv intrauterin	„Steriliet Yunona - T”	Sterileta Iunona T cu Cupru	
2		Contraceptiv intrauterin	„Steriliet Yunona - T”	Sterileta Iunona T cu Cupru Bio Multi	
3		Contraceptiv intrauterin	„Steriliet Yunona - T”	Sterileta Iunona T inel cu Cupru tip 2	
4		Contraceptiv intrauterin	„Steriliet Yunona - T”	Sterileta Iunona T super (pentru procese inflamatorii)	

ЗАО «Медицинское предприятие Симург»
разработка и производство медицинских изделий
Республика Беларусь, 210023, Витебск,
пр-т Генерала Людникова, 13, комната 413
тел./факс: +375 212 62 32 33
www.simurg-mp.com e-mail: info@simurg.by

CJSC «Medical enterprise Simurg»
the development and manufacture of medical products
The Republic of Belarus, 210023, Vitebsk,
pr. Generala Lyudnikova, 13, room 413
Tel./Fax: +375 212 62 32 33
www.simurg-mp.com e-mail: info@simurg.by

POWER OF ATTORNEY

To whom it may concern

I, Viachaslau Daradzeika, as a legal representative of CJSC "Medical enterprise Simurg", addressed in The Republic of Belarus, 210023, Vitebsk pr. Generala Lyudnikova, 13, room 413, empower Mrs. Luca Victoria , Specialist in Department of Certification and Registration within Becor Company (Authorized representative) with juridical address: CALEA ORHEIULUI STREET 111/5, 2020 CHISINAU, Republic of Moldova, passport no. B03007217, to represent the interests of CJSC "Medical enterprise Simurg" in front of Authorities of Republic of Moldova in all issues concerning licensing (authorization) and registration of products (medical device).
For the execution of the aforementioned things, Mrs Luca Victoria is authorized to sign in Company's name all necessary documents for registration, but only in the limits of this letter.

05.10.2023

Director
CJSC "Medical enterprise Simurg" V.G. Daradzeika

Statement of the completed project

SIA Simurg Balticum is proud to announce successufully completed project of the CE certification of our Class III medical device – Younona Intrauterine contraceptives.

Project was supported and finansed by LIAA under the project Nr. VP-PI-2021/42 and project of the technology transmission ID number Nr. 1.2.1.2/16/I/001.

NATIONAL DEVELOPMENT PLAN 2020

EUROPEAN UNION
European Regional Development Fund

INVESTING IN YOUR FUTURE

Prepared & Issued by	Control Status	Approved by
Sign	MASTER COPY	Sign
Quality Assurance Manager		Managing Director

QUALITY POLICY

Simurg Balticum SIA is committed to provide total customer satisfaction and enhance it through continual improvements and to maintain its effectiveness by involving everyone in the organization.

The quality policy of Simurg Balticum SIA is as mentioned below.

We, at Simurg Balticum SIA are highly committed to provide the Best Quality Medical Devices and Regular Services through a Controlled Environment, to all our Esteemed Customers.

We are committed to satisfy our customers and stakeholders with timely delivery of quality products, solutions and services.

We are committed to the continual improve of quality management system and maintain its effectiveness in terms of high quality and prompt services.

Prepared & Issued by	Control Status	Approved by
Sign	CONTROLLED COPY	Sign
Quality Assurance Manager		Managing Director