Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. din 29.09.2023

Solicitantul Ortofix SRL, cu sediul mun. Chisinau str. Mt. Gurie Grosu 15/4, tel./fax: 295-845, e-mail ortofix.moldova@gmail.com,
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

MIKRON Spinal instruments

A Se anexează următoarele acte:

contract de reprezentanta,
DOC MIKRON

Data 29.09.2023 Bolocan Vasile

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care deţin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: Ortofix SRL, cu sediul mun. Chisinau, str Mitropolit Gurie Grosu 15/4,

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

MIKRON Spinal instruments ;
_____ ;

Sunt autentice și corespund realității.

Vasile Bolocan, director

29.09.2023

Anexa nr.3

Numarul de catalog	Denumire	a comercial	Modelul	Tip dispozitiv	Cod GMDN
MSPS00	Spinal fixation set		Posterior universal spinal set	instrumente ortopedic	L0910
MSPD00	Spinal fixation set		Pediatric spinal set	instrumente ortopedic	L0910
MMIS000	Spinal fixation set		MIS derotation spinal set	instrumente ortopedic	L0910
MSAC00	Spinal fixation set		Cervical plate set	instrumente ortopedic	L0910
MSCP00	Spinal fixation set		Cervical cage set	instrumente ortopedic	L0910

Declaration of Conformity

Manufacturer	MİKRON MAKİNA SANAYİ VE TİCARET LİMİTED ŞİRKETİ
Head office:	İVEDİK OSB AĞAÇİŞLERİ SAN. SİT. 1372. SOK NO:31 OSTİM / YENİMAHALLE / ANKARA / TÜRKİYE
Manufacturing Address*:*	DAĞYAKA MAH.DAĞYAKA CAD.NO38 KAHRAMANKAZAN ANKARA TÜRKİYE
Products*:*	DESIGN, MANUFACTURE AND DISTRIBUTION OF SPINAL & TRAUMA IMPLANTS, SURGICAL INSTRUMENTS AND GENERAL INSTRUMENTS *Detailed product list is given in the attached list.*
Classification	CLASS 1
Certificate No:	**ISO 02 848 1089**
Certificate date:	**February 20, 2023**
Certificate expired date:	**February 19, 2026**

We herewith declare that above mentioned products meet the provisions of the EN ISO 13485:2016 **All supporting documentation is retained under our premises.**

Standards Applied EN ISO 13485:2016, TS EN ISO 11607-1: 2017, TS EN ISO 11607-2: 2017, TS EN ISO 14971: 2013, TS EN ISO 14630: 2013, TS 1980-1 EN 22768-1: 1995, TS EN ISO 10993-1: 2014, TS EN ISO 10993-3: 2015, TS EN ISO 10993-4: 2017, TS EN ISO 10993-6: 2017, TS EN ISO 10993-7: 2010, TS EN ISO 10993-10: 2014, TS EN ISO 10993-11: 2018, TS EN ISO 10993-12:2013, TS EN ISO 10993-15:2010, TS EN ISO 10993-17:2013, TS EN ISO 10993-18:2010, TS EN ISO 14602: 2012, TS EN ISO 11737-1: 2018, TS EN ISO 11737-2: 2010, TS EN ISO 11135: 2014, TS EN 1041+A1: 2014, TS EN ISO 15223-1: 2016, MEDDEV 2.4/1, MDD/93/42/EEC, 2007/42/EC, 2001/83/EEC, MEDDEV 2.5/5, MEDDEV 2.7/1, MEDDEV 2.7/3, MEDDEV 2.7/4, MEDDEV 2.12/1, MEDDEV 2.12/2, , CE İşareti Yönetmeliği, ASTM F543 - 13e1, ASTM F2193 – 14, ASTM F 1798-13, ASTM F136 – 13, ASTM F1980 – 16, ASTM F382 – 14

Notified Body	**Medicert Uluslararası Ürün ve Sistem Belgelendirme Ltd şti**.
Address:	Tersane Mah Cemal Gürsel Cad No: 11/3 Halide Hnm. Apt. Karşıyaka / İzmir

we declare that the products do not contain human blood derivatives, tissues of animal origin, phthalate and latex and do not emit radiation.

Place, Date of Issue ANKARA, TÜRKİYE / 1.07.2023

Name MUSTAFA EKİZ

Title Company Manager

Signature

Declaration of Conformity

ANNEX

MSAC00	MIKRON MIRACH CERVICAL PLATE SET
MSAC01	Cervical Plate Forcep Holder
MSAC02	Bone Awl
MSAC03	Cervical Plate Pin
MSAC04	Cervical Plate Screw Driver
MSAC05	Cervical Plate Screw Holder
MSAC06	Pin Holder
MSAC13	Cervical Plate Locker II
MSAC08	Cervical Drill and Tap Guide
MSAC09	Tap 3,0 mm
MSAC10	Drill 2,5 mm
MSAC11	Cervical Plate Bender
MSAC12	Single-Barrel Guide
MSAC07	Cervical Plate Locker I
MSAC14	Implant Case For Plate
MSCC00	MIKRON REGULUS CORPECTOMY SET
MSCC01	Corpectomy Cage Inserter
MSCC02	Corpectomy Nut Driver
MSCC03	Corpectomy Nut Holder
MSCC04	Cervical Corpectomy Cage Pusher
MSCC05	Lumbar Compectomy Cage Pusher
MSCC06	Cervical Corpectomy Cage Rotater
MSCC07	Lumbar Corpectomy Cage Rotater
MSCC08	Corpectomy Cage Length Measure
MSCC09	Implant Case For Cervical Corpectomy
MSCC10	Implant Case For Lumbar Corpectomy
MSCA00 SET	MIKRON AGENA CERVICAL PEEK CAGE
MSCA01	Cervical Stand Alone Cage Holder
MSCA02	Drill 2.5 mm
MSCA03	Tap 2.7 mm
MSCA04	Standalone cage screw holder
MSCA05	Standalone cage screw driver
MSCA06	Small Mallet
MSCA07	Caspar Pin Holder
MSCA08	Caspar Pin
MSCA09	Cervical Caspar Retractor
MSCA10	Cervical Pasp
MSCA11	Cervical Trial 4 mm
MSCA12	Cervical Trial 5 mm
MSCA13	Cervical Trial 6 mm
MSCA14	Cervical Trial 7 mm
MSCA15	Cervical Trial 8 mm
MSCA16	Implant Case
MSCP00 SET	MIKRON AGENA CERVICAL PEEK CAGE
MSCP01	Cervical Peek Holder
MSCP02	Cervical Bladed Peek Holder

MSCP03	Cervical Expandable Peek Cage Holder
MSCP04	Small Mallet
MSCP05	Caspar Pin Holder
MSCP06	Caspar Pin
MSCP07	Cervical Caspar Retractor
MSCP08	Cervical Pasp
MSCP09	Cervical Trial 4 mm
MSCP10	Cervical Trial 5 mm
MSCP11	Cervical Trial 6 mm
MSCP12	Cervical Trial 7 mm
MSCP13	Cervical Trial 8 mm
MSPC00	MIKRON OMICRON POSTERIOR CERVICAL SET I/ II
MSPC01	Cervical Bone Awl
MSPC02	Cervical Probe Curved
MSPC03	Cervical Probe Straight
MSPC04	Drill 2,2x200 mm
MSPC05	Drill 2,7x200 mm
MSPC06	Tap 3,0 mm
MSPC07	Tap 3,5 mm
MSPC08	Drill Guide Tap Guide
MSPC09	Cervical Feeler Curved
MSPC10	Cervical Feeler Straight
MSPC11	Cervical Polyaxial Screw Driver
MSPC12	Cervical Set Screw Holder
MSPC13	Handle Straight
MSPC14	Final Set Screw Driver Shaft
MSPC15	Torque 3 Nm I type
MSPC16	Torque 3 Nm Round
MSPC17	Cervical Anti Torque
MSPC18	Forcep Rod Holder 3,0mm
MSPC19	Rod Pusher 3,0mm
MSPC20	Rod Bender 3,0mm
MSPC21	Rod Cutter 3,0 mm
MSPC22	Rod Template 3,0 mm
MSPC23	Cervical Persuader
MSPC24	Small In-Situ Bender Left
MSPC25	Small In-Situ Bender Right
MSPC26	Cervical Compressor
MSPC27	Cervical Distractor
MSPC28	Cervical Transverse Link Holder Forceps
MSPC29	Connector Nut Driver 2,5
MSPC30	Occipital Plate Bender
MSPC31	Occipital Plate Screw Holder
MSPC32	Drill 2,2x150 mm Occipital
MSPC33	Drill 2,7x150 mm Occipital
MSPC34	Tap 3,0 mm Occipital
MSPC35	Tap 3,5 mm Occipital
MSPC36	Drill And Tap Guide Occipital
MSPC37	Occipital Plate Screw Driver
MSPC38	Implant Case For Cervical Screw
MSPP00	MIKRON PEDIS POSTERIOR PEDIATRIC SET I/II
MSPP01	Pedis Bone Awl
MSPP02	Probe Straight Thinner

Declaration of Conformity

MSPP03	Probe Curved Thinner
MSPP04	Marker
MSPP05	Marker With Stopper
MSPP06	Tap 3 mm
MSPP07	Tap 4 mm
MSPP08	Tap 5 mm
MSPP09	Tap 6 mm
MSPP10	Pedis Feeler Straight
MSPP11	Pedis Feeler Curved
MSPP12	T Handle
MSPP13	Pedis Polyaxial Screw Driver
MSPP14	Forcep Rod Holder
MSPP15	Rod Pusher 5,0
MSPP16	Pedis Set Screw Holder 5,0
MSPP17	Pedis Set Screw Driver 5,0
MSPP18	Torque 9 Nm
MSPP19	Pedis Final Set Screw Driver Shaft
MSPP20	Pedis Anti-Torque
MSPP21	Rod Gripper
MSPP22	Rocker
MSPP23	Persuader
MSPP24	4 Nm Torque
MSPP25	Set Screw Driver For Connector
MSPP26	Rod Bender
MSPP27	Compressor
MSPP28	Distractor
MSPP29	Lysthesis Screw Cutter
MSPP30	In-Situ Bender Right
MSPP31	In-Situ Bender Left
MSPP32	Mallet
MSPP33	Rachet Handle T Type
MSPP34	Rod Template
MSPP35	Screw Tray
MSPS00	MIKRON PROCYON / POLAR POSTERIOR SPINAL SET
MSPS01	Bone Awl
MSPS02	Probe Straight
MSPS03	Probe Curved
MSPS04	Marker
MSPS05	Marker With Stopper
MSPS06	Tap 4 mm
MSPS07	Tap 5 mm
MSPS08	Tap 6 mm
MSPS09	Feeler Curved
MSPS10	Feeler Straight
MSPS11	T Handle
MSPS12	Polyaxial Screw Driver
MSPS13	Monoaxial Screw Driver
MSPS14	Rod Holder Forceps
MSPS15	Rod Pusher
MSPS16	Set Screw Holder
MSPS17	Set Screw Driver
MSPS18	12 Nm Torque
MSPS19	Final Set Screw Driver Shaft 6,0
MSPS20	L Anti-Torque
MSPS21	Rod Gripper

MSPS22	Rocker	MSPT04	Tlif Cage Pusher
MSPS23	Rocker Forceps	MSPT05	Curette Straight
MSPS24	Persuader	MSPT06	Curette Left
MSPS25	4 Nm Torque	MSPT07	Curette Right
MSPS26	Transverse Nut Driver	MSPT08	Tlif Rasp
MSPS27	Rod Bender	MSPT10	Mallet Small
MSPS28	Compressor	MSPT12	T Handle
MSPS29	Distractor	MSPT13	I Handle
MSPS30	Lysthesis Screw Cutter	MSPT11	Sliding Mallet
MSPS31	In-Situ Bender Right	MSPT14	Disc Shaver 7 mm
MSPS32	In-Situ Bender Left	MSPT15	Disc Shaver 8 mm
MSPS33	Multiaxial Link Driver Shaft	MSPT16	Disc Shaver 9 mm
MSPS34	Mallet	MSPT17	Disc Shaver 10 mm
MSPS35	Handle	MSPT18	Disc Shaver 11 mm
MSPS36	Rod Template	MSPT19	Disc Shaver 12 mm
MSPS37	Screw Tray	MSPT26	Tlif Trial 7 mm
MSPT00	MIKRON CAPELLA PLIF SET	MSPT27	Tlif Trial 8 mm
MSPT01	Plif Cage Inserter	MSPT28	Tlif Trial 9 mm
MSPT02	Plif Expandable Inserter	MSPT29	Tlif Trial 10 mm
MSPT09	Plif Rasp	MSPT30	Tlif Trial 11 mm
MSPT20	Plif Trial 7 mm	MSPT31	Tlif Trial 12 mm
MSPT21	Plif Trial 8 mm	MSUD00	MIKRON ESTELA INTERSPINOUS SET
MSPT22	Plif Trial 9 mm	MSUD01	Bending Plier Compressor
MSPT23	Plif Trial 10 mm	MSUD02	Crimping Plier Distractor
MSPT24	Plif Trial 11 mm	MSUD03	U Device Trial 8 mm
MSPT25	Plif Trial 12 mm	MSUD04	U Device Trial 10 mm
MSTP00	MIKRON TUREIS TLIF SET	MSUD05	U Device Trial 12 mm
MSPT03	Tlif Cage Inserter	MSUD06	U Device Trial 14 mm

MSUD07	U Device Trial 16 mm
MSUD08	Mallet
MSPS39	Rod Cutter
MSPS40	Table Rod Cutter
MSPS41	Persuader
MSDP01	Cervical Disc Prosthesis Holder
MSSS00	Mikron Scoliosis Set
MSSS01	Reducer Clip Tower With Sleeve
MSSS02	Derotation Tube
MSSS03	Handle Connector
MSSS04	Modular Handle Short For Reduction Screw
MSSS05	Persuader
MSSS06	Rod Gripper
MSSS07	T Handle
MSSS08	Arti T Handle
MSSS09	Set Screw Driver
MSSS10	En Bloc Connector
MSSS11	Segment Connector
MSSS12	Set Screw Holder
MSSS13	Coronal Rod Bender Right
MSSS14	Coronal Rod Bender Left
MMIS000	MIS SPINAL SET
MMIS01	Net Plate
MMIS02	Guide Wire Extractor
MMIS03	Puncture Pin
MMIS04	Minimally Invasive Guide
MMIS05	Adjusting Screwdriver
MMIS06	Hard Probe
MMIS07	Guide Wire (Ø 1.5)
MMIS08	Compression Forcep
MMIS09	Screw Inserter
MMIS10	Screwdriver
MMIS11	Open Awl
MMIS12	Tap (Ø4.5)
MMIS13	Tap (Ø5.0)
MMIS14	Tap (Ø5.5)
MMIS15	Tap (Ø6.0)
MMIS16	Tap (Ø6.5)
MMIS17	Tap (Ø7.0)
MMIS18	Tap (Ø7.5)
MMIS19	Refurbishment Screwdriver (T27)
MMIS20	Final Screwdriver
MMIS21	Single End Plug Screwdriver
MMIS22	Parallel
MMIS23	Counter Spanner
MMIS24	Multilayer Sleeve (Ø5.8)
MMIS25	Multilayer Sleeve (Ø9)
MMIS26	Multilayer Sleeve (Ø12)
MMIS27	Multilayer Sleeve (Ø15.2)
MMIS28	Multilayer Sleeve (Ø18.5)
MMIS29	Multilayer Sleeve (Ø21.8)
MMIS30	Rod Holder (5.5)
MMIS31	Unlocker
MMIS32	Crossed Connecting Device (Short)
MMIS33	Rod Bending Forcep

MMIS34	Parallel Connecting Device
MMIS35	Torque T Handle 12Nm
MMIS36	Curved Connecting Device
MMIS37	Parallel Gauge
MMIS38	Crossed Gauge
MMIS39	Crossed Connecting Device (Long)
MMIS40	Minimally Invasive Rod Insertion Device
MMIS41	Continuous Self Breaking Screwdriver
MMIS42	Quick Coupling Handel (T-shape)
MMIS43	Distracting Forceps (Long)
MMIS44	Distracting Forceps
MMIS45	Mini Ratchet Handel

DISTRIBUTION AGREEMENT

(hereinafter referred to as Company A)

MİKRON MAKİNA SANAYİ VE TİCARET LİMİTED ŞİRKETİ
İVEDİK OSB AĞAÇ İŞLERİ SAN. SİT. 1372. SOK NO:31 OSTİM
YENİMAHALLE - ANKARA / TURKEY
and

(hereinafter referred to as Company B)

- **Ortofix SRL,**
  str. Mt Gurie Grosu 15/4
  mun. Chisinau, Republic of Moldova, MD 2028

Have agreed as follow, regarding the safe handling of the medical devices (hereinafter called "Products") manufactured and supplied by Company A to Company B in order to comply with the requirements of the Government Decision no.418 of 05 June 2014 concerning Medical Devices (GDMD) and the "Guidelines on a Medical Devices Vigilance System".

APOINTMENT

Company A hereby appoints Company B upon the terms and conditions herein contained to be official representative for the products manufactured by Company A.

And whereas Company B expresses their desire to enter into an agreement with Company A upon the terms and conditions set forth in this Agreement.

RESPONSIBILITIES OF BOTH PARTIES - GENERAL INFORMATION

Company B is authorized to perform registration, renewal, variation of the registration.
Company A shall provide to company B for the registration of medical devices the following information:

a) Declaration of conformity,
b) Copy of the label, packaging and instructions for use (in all languages requested by the countries where the device is marketed),
c) Notified Body certificates (where relevant),
d) Post market surveillance process and data, vigilance reports and complaints, processes and data,

e) Technical documentation relevant to market surveillance investigation being undertaken by the Medicines and Medical Devices Agency (Agency),
f) Relevant clinical data/notification,
g) Details of any distributors/suppliers putting the Republic of Moldova marked devices on the market,
h) Incident reports and reports on corrective actions taken.

Company B shall be responsible for registration, monitoring and to communicate all claims for the customers and market related of the products of Company A and to notify Company A upon receiving such claims.

Incident Reporting

Company B shall maintain an update Quality System and communicate the vigilance procedures to Company A for coordination and continuity of Company A's own Quality System. Company B shall communicate any of other procedures upon request of the Company A.

Company B shall work closely with Company A and shall transmit without delay any information coming from the Agency. In case of special request by the Agency, particularly in relation with incidents reporting, the Company B will agree with Company A on the position statement and answers to give to the Agency.

In case of difference in positions between Company A and Company B, the position of Company A will prevail and will be supplied to the Agency with a format endorsement of the Company A.

Company B shall have a qualified person to be in contact with the Agency.

In case of incidents known first by the Company A, the Company B will be immediately informed and will immediately perform with the Company A the analysis of the accident. The Company B will write and send to the concern Agency the initial report including Company A actions if available such as sample analysis, analysis of historic lot record and potential corrective actions to be taken in the further manipulation of the product like withdraw, recall from the market.

Company B shall notify Agency about the following time lines apply in a case of:

a) Serious public health threat: IMMEDIATELY (without any delay that could not be justified) but not later than 2 calendar days after awareness by the company A of this threat.
b) Death or UNANTICIPATED serious deterioration in state of health: IMMEDIATELY (without any delay that could not be justified) after the company A established a link

between the device and the event but not later than 10 elapsed calendar days following the date of awareness of the event.

c) Others: IMMEDIATELY (without any delay that could not be justified) after the company A established a link between the device and the event but not later than 30 elapsed calendar days following the date of awareness of the event.

If after becoming aware of a potential reportable INCIDENT there is still uncertainty about whether the event is reportable, Company A must submit a report with the timeframe required for the type of INCIDENT.

As soon as information and incidents assessment from Company A are available, Company B writes and sends the final incidents report. In any case, Company B submits these reports to Company A for preliminary approval. Company B will keep these records available for the Agency.

According to the stipulation of medical equipment plant GDMD, the Company A must summarize the experience of manufacturing products, take proper measures, and have the right to know the incident occasionally happened, and take proper measures.

a) The mangle of property of medical equipment, improper logo, and misuse without the guide of instruction for use can lead to lead to the death of patients and users and deterioration of health condition.

b) The above-mentioned, the technical property of the products or the problems in medicine, the company has the right to recall the products of the same lot and specification.

Field safety notice

The Company A finds that there is a problem of quality of the products on the market, it should immediately give out a Field Safety Notice for the users, so they could be able to take the necessary measures (including the recall of the products).

Recall

In case of products are withdrawn from the market, the Company A should recall the products immediately. Before recalling the products, the Company B should inform the Agency.

Return the products to the company

Company A shall send advisory notice to Company B in this region and order him to cease selling the products. Recall the products sold to the market or inform the users, ask the Company B in this region to inform the local governing department where the products are sold.

After the Company B recalls the products, Company A should agree with the Company B on the mode of transportation or time, and return the products to the company for disposal.

Traceability of Sold Products

Company A shall keep records of serial numbers, batch numbers for all products delivered to Company B.

Company B shall keep records of the Products delivered to the users or distributors. In this case the traceability of sold products can be performed at any time upon request. Records shall include the following information:

Name and address of the customer

Quantity dispatched

Date transferred to the customer

Serial or production lot numbers

It is agreed that these records should be available for inspection upon request by Company A or by the relevant authorities.

Technical Documentation

Company A shall establish necessary procedures to prepare and maintain Technical Documentation including the Declaration of Conformity for the products manufactured by Company A to be able to comply with the GDMD requirements.

Company A shall transfer the agreed Technical documentation and Declaration of Conformity to Company B.

Company B shall keep the Technical Documents including the Declaration of Conformity available to the Agency for at least five years after the last products has been sold.

Company A shall provide to Company B and additional documentation if required by Agency.

Instruction Manual

Company A shall be responsible for content of instructions manual (user's guide) and shall ensure the availability of the English version of the instruction's manual for Company B.

Company B shall ensure the required instruction manuals to be provided to the customer in official language of the Republic of Moldova.

mikron medical

for the following Product Categories:
product group and models/types
All spinal line products
All trauma line products

MİKRON
MAKİNA SAN. VE TİC. LTD. ŞTİ.
Dağyaka Mahallesi Dağyaka Caddesi No:38
Kahramankazan / ANKARA
Tel: 0312 395 17 00 Fax: 0312 395 67 29
Ulus V.D. 621 002 8867

Mikron Makina Ltd **Ankara 20.06.2022** **Yakup Yılmaz , Director**

REPUBLICA MOLDOVA, CHIŞINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ, ORTOFIX, S.R.L.

Ortofix SRL **Chisinau, 22.06.2022** **Roman Bolocan, Director**