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:

Z-Medical Spinal instruments

A Se anexează următoarele acte:

contract de reprezentanta,
DOC Z-Medical

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:

Z-Medical Spinal instruments ;
_____ ;

Sunt autentice și corespund realității.

Vasile Bolocan, director

29.09.2023

Numarul de catalog	Denumire	Denumirea co	Modelul	Tip dispozitiv	Cod GMDN
A06 088	Screwdriver		Pedicle spine instrument	Instrumente ortopedice	L0919
A06 306	Z-handle		Pedicle spine instrument	Instrumente ortopedice	L0919
A06 090	T-handle		Pedicle spine instrument	Instrumente ortopedice	L0919
A06 370	T handle with Torque		Pedicle spine instrument	Instrumente ortopedice	L0919
A06 380	Rod Bender		Pedicle spine instrument	Instrumente ortopedice	L0919
A06 384	Rod Inserter		Pedicle spine instrument	Instrumente ortopedice	L0919
A06 385	Counter support		Pedicle spine instrument	Instrumente ortopedice	L0919
A06 389	Distractor-Compressor		Pedicle spine instrument	Instrumente ortopedice	L0919
A06 487	Adapter		Pedicle spine instrument	Instrumente ortopedice	L0919
A06 500	Tulip breacker		Pedicle spine instrument	Instrumente ortopedice	L0919
A06 508	Awl set		Pedicle spine instrument	Instrumente ortopedice	L0919
A06 509	Thread drill		Pedicle spine instrument	Instrumente ortopedice	L0919
A06 510	Reamer		Pedicle spine instrument	Instrumente ortopedice	L0919
A06 512	T-handle with ratchet		Pedicle spine instrument	Instrumente ortopedice	L0919
A06 513	Tulip adaptor		Pedicle spine instrument	Instrumente ortopedice	L0919
A06 524	Clamping tube		Pedicle spine instrument	Instrumente ortopedice	L0919
A06 530	Chuck rod		Pedicle spine instrument	Instrumente ortopedice	L0919
A06 600	Container set		Pedicle spine instrument	Instrumente ortopedice	L0999

EG Konformitätserklärung
Declaration of conformity

ISO / IEC Guide 22

Gänsäcker 38 - 78532 Tuttlingen

We *Wir*

Supplier / *Anbieter :* **Z- Medical GmbH + Co.KG**

Address / *Anschrift:* **Gänsäcker 38**
D - 78532 Tuttlingen

herewith declare under our sole responsibility, that our Medical Devices of the Product Group
erklären hiermit unter eigener Verantwortung, dass unsere Medizinprodukte der Produktgruppe

Wirbelsäulen Set	**GMDN / UM-DNS Code**	**Description** ***Bezeichnung***	**Class** ***Klasse***	**Rule** ***Regel***
	- / -	*Spine instruments*	1	6

have been manufactured under consideration of European Medical Device Directive 93/42/EEC. The Products are conform to the Medical Device Directive 93/42/EEC and Essential Requirements of the Annex I and may therefore be placed into market, labelled with CE. The conformity assessment of the devices has been performed according to MDD 93/42/EEC, Annex VII.
unter Berücksichtigung der EG-Richtlinie 93/42/EWG gefertigt wurden. Die Produkte sind konform mit der EG-Richtlinie 93/42/EWG und den Grundlegenden Anforderungen des Anhang I und dürfen somit mit CE gekennzeichnet, von uns in Verkehr gebracht werden. Das Konformitätsbewertungsverfahren unserer Produkte erfolgt nach RL 93/42/EWG, Anhang VII.

Product List / Produktliste:
A06 088, A06 306, A06 090, A06 370, A06 380, A06 384, A06 385, A06 389, A06 487, A06 500, A06 508, A06 509, A06 510, A06 512, A06 513, A06 524, A06 530, A06 600

This declaration of conformity is valid until 26.05.2024
Diese Konformitätserklärung ist gültig bis 26.05.2024

Date and Place / Datum und Ort: 24.05.2021 Tuttlingen

V. Vinche (PRRC)
(Signature / *Unterschrift*)

1. List of Changes

Significant or major changes will be documented and indicated using a new main revision likewise v1.0, v2.0. Changes will be considered to be significant or major if:

- New products or product category will be included within this STED;
- New Intended Use will be defined;
- New / different materials will be used;
- New manufacturing method will be used;
- New production manufacturing base will be used;
- New sterilization process will be used;
- New sterilization facility will be used.
- New information from the post marketing surveillance and reported complaints is initiating a major change.

Minor or editorial changes will be documented and indicated using a new secondary revision likewise vx.1, vx.2.

Date	Rev.	Description of Change	Changed by
2016-03-04	03	Änderungen aufgrund RP Audit	Kirill Kipke
2019-03-11	04	Aktualisiert	Kirill Kipke
2019-10-18	05	An die Produktliste angepasst	Kirill Kipke
2020-02-04	06	Ort hinzugefügt. ZC entfernt.	Kirill Kipke
2020-03-26	07	Gültigkeitsdatum aktualisiert	Kirill Kipke
2020-07-06	08	PRRC hinzugefügt	Kirill Kipke
2021-03-19	09	A06 320 hinzugefügt	Kirill Kipke
2021-04-13	10	Stabeinbringer Artikelnummern korrigiert.	Kirill Kipke
2021-05-24	11	Folgende Produkte von der DoC genommen: A06 373, A06 381.	Kirill Kipke

SURGICAL
INNOVATIONS

Agreement

(hereinafter referred to as Company A)
manufacture name and address

Z-Medical GmbH + Co.KG
Gänsäcker 38
D-78532 Tuttlingen

and

(hereinafter referred to as Company B)
- authorized representative name and address
Ortofix SRL
Str. Mt. Gurie Grosu 15/4
MD 2028 Chişinău

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 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) Details of any distributors/suppliers putting the Republic of Moldova marked devices on the market,
e) Incident reports and reports on corrective actions taken

Company A confirms that the following processes are in place, data are generated and are regularly updated:

f) Post market surveillance process and data, vigilance reports and complaints, processes and data,
g) Technical documentation relevant to market surveillance investigation being undertaken by the Medicines and Medical Devices Agency (Agency),
h) Relevant clinical data/notification.

This is regularly inspected by our Notified Body and the CE Certificates serve as confirmation that processes and data are adequate and conform with actual laws and standards.

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.

SURGICAL
INNOVATIONS

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 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 feasible and 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 instructions 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.

for the following Product Categories:
product group and models/types

Z-Pedicle screws and rods spinal system;

Z-Medical	*: Name and Position*	*place, date*	*Signature*
	President *ZbigniewJosef* *Combrowski*	*Tuttlingen,* *20.07.2022*	Z. J. Com
Ortofix	*: Name and Position*	*place, date*	*Signature*
	President		

Chișinău
21.07.2022