

Won a Tender, Shipped the Goods — and Got an Inspection by the State Service

How a missing medical device registration can cost a manufacturer not only fines, but also a government contract

How it happened

A Ukrainian manufacturer of rehabilitation medical devices (Class I) came to us. An experienced company that has been on the market for several years and has regular clients. It won a public tender, signed the contract and shipped the goods to the customer.

It looked like a success. But the joy did not last long.

Competitors filed a complaint with the State Service of Ukraine on Medicines and Drugs Control. The inspection showed that the products were not in the medical device register. The technical file did not meet the requirements of the current Technical Regulation (TR 753). The Declaration of Conformity had been drawn up with violations.

Now, instead of waiting for payment, the company had to fix all of this urgently. And it faced a real threat of fines.

Why this happens

Class I medical devices in Ukraine go through self-declaration: the manufacturer draws up the Declaration of Conformity itself and enters the products into the State Service register. No Conformity Assessment Body is involved. It seems simple. But this very “simplicity” is the trap.

Some manufacturers skip this step:

- some think they will “get away with it” as long as there is no inspection
- some are in a hurry to enter the market and put registration off “for later”
- some simply do not know that even Class I needs to be entered into the register

All this “works” — right up until competitors, an unhappy customer or a planned market surveillance check appear.

What the State Service checks

During an inspection, inspectors ask for:

- ✓ Declaration of Conformity
- ✓ Technical file (complete, as required by TR 753)
- ✓ Proof of entry into the medical device register
- ✓ Labelling and instructions for use
- ✓ Shipping documents (contracts, invoices)

The absence of any of these documents is grounds for sanctions.

What fines apply

Under the Law of Ukraine “On State Market Surveillance and Control of Non-Food Products”:

Violation	First violation	Repeat (within 1-3 years)
The product does not meet the requirements (no registration, technical file violations)	UAH 51,000	UAH 102,000
The product poses a serious risk	UAH 102,000	UAH 340,000

⚠ Important: the fine is imposed separately for each model, article number or batch. If 5 unregistered items are in the product range, multiply the amount accordingly.

Besides fines, the State Service has the right to:

- ban further sales of the products
- require recall of products already delivered to the market
- initiate termination of the government contract
- entry into the Prozorro register of unreliable suppliers, which in practice closes access to public procurement for years

What we did

The client came to us right after receiving the inspection results. We carried out a full regulatory audit and developed an action plan:

- 1 Analysis of the existing technical documentation and identification of non-conformities
- 2 Bringing the Technical File in line with the requirements of TR 753
- 3 Review and correction of the Declaration of Conformity
- 4 Preparation and submission of the application for entry into the State Service register
- 5 Support until the registration record is issued

Check yourself right now

If you manufacture medical devices for the Ukrainian market — even Class I — and plan to take part in tenders or sell products on the market:

- ☐ Are your products entered into the State Service register?
- ☐ Is the technical file prepared in line with TR 753?
- ☐ Is the Declaration of Conformity up to date and correctly drawn up?
- ☐ Does the labelling meet the requirements?

If the answer to at least one question is “not sure” or “no”, it is better to solve it before the tender than after shipment.

Remember: competitors never sleep.

Need help with registration or a documentation audit?

Contact us — we will look at your situation and prepare the documents in line with the State Service requirements.

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