NOTICE of

adverse event (incident)
related to the use of a medical device

(confidential — only for safety monitoring)

The number of notice of AE in the Automated Information System

□□.□□.□□□□
Date of registration in the Automated Information System

Source of information
- □manufacturer (representative)
- □distributor (supplier)
- □healthcare provider
- □provider
- □insurance company
- □medical professional
- □patient
- □individual user
- □regulatory body
- □other (specify):

Outcome
- □fatal
- □disability
- □recovered with sequelae
- □not recovered or not resolved
- □recovering or resolving
- □recovered or resolved
- □not applicable
- □unknown
- □other (specify):

Notice type
- □primary
- □subsequent
- □final service

Previous notice number
(for all except for the primary)

Event description:

□□.□□.□□□□
Event date

AE identification number
(internal in the facility)

Injured Person:
- □home care patient
- □outpatient
- □inpatient
- □healthcare professionals
- □visitor
- □technical staff
- □individual user
- □other (specify):
- □none

The damage caused:
- □fatal
- □life threatening injury
- □irreparable injury
- □need for medical intervention
- □need for inpatient hospitalization
- □disability
- □fetus abnormalities, fetal death
- □other (specify)
- □none

Event location:
- □in the health facility
- □in-home
- □other (specify):

Device failure
- □impaired function
- □incorrect readings
- □other (specify):
- □none

Device information:

Device type code

Medical device name
Classification of Medical Devices by Type

Device brand, model name
GMDN

Nomenclature

Serial number / Batch number

Software version

Part number

Supplier (OKPO number, name)

MD State Registry number (N RU)

□□.□□.□□□□
Production date

□□.□□.□□□□
Purchase date

□□.□□.□□□□
Expiry date

Device risk class
□1 □2a □2b □3

Shared devices (if applicable):

Service life

Lifespan (if applicable)

□ This device has been previously used
□ Single-use device
□ The device was used unassisted

□□.□□.□□□□
Date of the last use the AE

Total operating time at the time of

□ Implantable device

□□.□□.□□□□
Implantation date

Current device location

□□.□□.□□□□
Explantation date

□□.□□.□□□□
Date of the last maintenance

Maintenance organization

Malfunctions identified during maintenance:

Reason for maintenance
- □scheduled maintenance
- □malfunction
- □other (specify):

Service contract No.

Availability of the device for research

The number of notice of AE in the Automated Information System

Notice of the Adverse event (incident)
(continued)

Health facility:

Health facility name | ZIP code, registered address

OKPO (RNNBO) code | Department name | Department actual address

OKFS Code
(Russian National Classifier of Ownership Patterns) | Phone No., Fax | E-mail | Website

Full name of the Qualified Person for the safety | Position of the Qualified Person for the safety

Injured Person:

Injured Person Name | Injured Person address/ job position

Injured Person ID | Diagnosis prior to the event

The state prior to the event

□M / □F
Sex, Age (completed years) | Physical characteristics of the injured person | Contraindications

User:

User Full Name

User identification number | User job position/ address

User contact information

User type:
- □medical professional
- □caregiver
- □individual user
- □technical staff
- □none other (specify):

Manufacturer:

Manufacturer name | ZIP code, address

Country of origin | Phone No., Fax | E-mail | Website

Representative in the Russian Federation:

Representative organization name | ZIP code, address

OKPO (RNNBO) code | Phone No., Fax | E-mail | Website

Full name of the Qualified Person for the safety | Position of the Qualified Person for the safety

Safety report No.

□□.□□.□□□□
Safety report date

The number of similar AEs for the same reason with the same devices

Measures taken:
- □MD recall
- □recovery
- □replacement
- □labelling change
- □amendments to the manual
- □notification
- □investigation
- □patient management
- □modification/adjustment
- □disposal
- □not required
- □other (specify):

Measures addressee:
- □medical professional
- □individual user
- □service provider
- □supplier
- □other (specify):

Notice numbers
in the Automated Information System of Roszdravnadzor subject to the measures taken:

Safety statement:

The statement issued by:

The person reporting on the AE:

Full name of the person reporting on the AE | Job position of the person reporting on the AE

Manufacturer's authorised rep.
Health facility authorised rep. Other:

Phone No., Fax | E-mail | Signature