



# COMPLAINT FORM

F2/PS 8.2.2.1

Rev. 1

## NOTIFIER'S INFORMATION

Name of organization / First and last name / Address

e-mail

phone

## PRODUCT IDENTIFICATION DATA

Name of the medical device

REF No.

LOT No.

Quantity

## DESCRIPTION OF THE COMPLAINT

Issue occurrence date

Notification date

Detailed description of nonconformity/incident

Circumstances of occurrence

before use     after use

## INCIDENT IMPACT

Was a patient or user harmed as a result of the incident?

NO     YES

Did the incident require medical intervention?

NO     YES

If so, please describe:

## DATA FOR ANALYSIS

Is the product eligible for return?

NO     YES

Have photos or other evidence been attached?

NO     YES

If so, please specify/describe:

Additional information / Comments

RLS: