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: