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EVENTS REPORTING FORM TO A MEDICAL DEVICE

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Please send this form to pharmacovigilance@rompharm.ro or turn to Rompharm medical representative. If you wish to report a quality defect that you noticed before the administration of the medical device, please provide a full description of the incident in the Event Description section.

PRIMARY REPORTER INFORMATION (HCP ☐ / Patient ☐ / Distributor ☐ / Other ☐.........................)			
NAME		EMAIL	
COUNTRY/ADDRESS(where the event occurred):			
PHONE NUMBER		SIGNATURE/ STAMP	
DATE OF REPORT (Date of first awareness)			

MEDICAL DEVICE INFORMATION			
Medical device Brand Name			
Operator of device at the time of the adverse event/reaction	☐ Healthcare professional ☐ Patient ☐ Other, please describe ________________		
Usage of device	☐ Initial use ☐ Reuse of a single use medical device ☐ Problem noted prior to use		
Expiry Date (dd/mm/yyyy)		Batch No or Serial no	
Route(s) of administration		Dose/ Number of medical devices administered:	
Administration date:			
Indication for which medical device was administered		Medical Device Current Location (i.e. healthcare facility, distributor, patient/user, discarded, in transit to manufacturer, remains implanted, manufacturer, unknown)	
Distributor (Name, address, phone number, email, fax, contact person)		Manufacturer (Name, address, phone number, email, fax, contact person)	

ASSOCIATED MEDICAL DEVICES (if applicable)			
☐ Needle - Batch no		Expiry Date (dd/mmm/yyyy)	______/________/_________

MEDICAL DEVICE EVENT/REACTION/ QUALITY DEFECT DESCRIPTION				
Location of adverse reactions:				
Was the event/issue noted:	☐ Before use	☐ During use	☐After use	☐Other:

Adverse event/reaction description	Onset date	Stop Date or Duration		Severity / intensity	Outcome *
			☐ ON-GOING ☐ UNKNOWN	☐ MILD ☐ MODERATE ☐ SEVERE	
			☐ ON-GOING ☐ UNKNOWN	☐ MILD ☐ MODERATE ☐ SEVERE	
			☐ ON-GOING ☐ UNKNOWN	☐ MILD ☐ MODERATE ☐ SEVERE	
			☐ ON-GOING ☐ UNKNOWN	☐ MILD ☐ MODERATE ☐ SEVERE	

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*Outcome Coefficient	1 = No serious outcome 2 = Indirect harm 3 = Required intervention to prevent permanent damage 4 = Disability or Permanent damage 5 = Hospitalization–initial or prolonged 6 = Life-threatening 7 = Death

Please provide a comprehensive description of the incident, including (1) what went wrong with the device (if applicable) and (2) a description of the health effects (if applicable), i.e. clinical signs, symptoms, conditions as well as the overall health impact (outcome).

Current health status of the patient	☐ Recovered/Resolved ☐ Recovering/Resolving ☐ Not recovered/Not resolved/Ongoing			☐ Recovered/resolved with sequelae ☐ Fatal ☐ Unknown
	Death	Yes ☐	No ☐	Date (dd/mmm/yyyy) ______/________ /_________

PATIENT INFORMATION (if appropriate)

Date of Birth (dd/mmm/yyyy)	______/____/________	Gender	Male ☐ Female ☐	Height	_______cm
Age at time of event (year)		Weight	_______Kg	Ethnic origin	

PATIENT MEDICAL HISTORY (if applicable) NONE ☐ UNKNOWN ☐ (*including pre-existing condition, previous known reactions, allergies, cutaneous and other pathologies*)

Corrective treatments/remedial actions:

CONCOMITANT DRUGS (if applicable) NONE ☐ UNKNOWN ☐

Drug	Dose	Frequency	Route of Admin.	Start Date	Stop Date	Indication