APPROVAL

Role	Name	Function	Signature
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Review	Julien Finci	CTO	
Approval	Mathieu Horras	CEO	

PURPOSE

This process identifies the requirements and tasks of the Person Responsible for Regulatory Compliance (PRRC) under the EU Medical Devices Regulation 2017/745 (Article 15) and the interfaces with other ASPIVIX SA processes. The monitoring and control of the manufacturing of the devices, their post-market surveillance and related vigilance activities play an important role here.

SCOPE

This procedure applies to employees within ASPIVIX SA who will be assigned for PRRC role and PRRC deputy role. According to the size of company, these roles might be outsourced. This procedure also applies if the roles are subcontracted.

Transition Rules
The process is valid from 26.05.2021, the date of application of the MDR 2017/745. The PRRC and the deputy must be appointed by this date and be able to perform their tasks.

RESPONSIBILITIES

Responsible for implementing this process is the Head of Human Resources who is ASPIVIX's CEO.

DOCUMENT HISTORY

Description of Changes	Version
Initial version	A
Remove of date in approval table and update logo. The procedure has been reviewed and is still applicable.	B

TABLE OF CONTENT

1 PROCEDURE DESCRIPTION

1.1 QUALIFICATIONS OF THE PRRC

The person responsible for regulatory compliance must possess the requisite expertise in the field of medical devices. The requisite expertise must be demonstrated by providing records for either of the following qualifications:

a. A diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognized as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;
or
b. Four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

1.2 APPOINTMENT AND ANNOUNCEMENT OF PRRC

The appointment of the PRRC will be recorded in writing, signed by the responsible persons and published in the organizational chart. Only then it will be recognized as acceptable.

1.3 DIVISION OF THE TASKS AMONG SEVERAL PERSONS

Delegation of tasks is possible, but the responsibility for their proper fulfillment remains with the designated PRRC. If several PRRCs are appointed, they will be jointly responsible for compliance with the regulatory requirements. Respective areas of responsibility are stipulated in writing.

1.4 PROHIBITION OF DISCRIMINATION

The PRRC must not suffer any disadvantages in connection with the proper fulfillment of his/her duties within the organization.

1.5 DEPUTY

The responsible person must nominate another person, who him-/herself is qualified for the PRRC role, to act as a deputy. The deputy must also confirm this role in writing and be visible in the organizational chart.

1.6 MINIMUM SET OF PRRC RESPONSIBILITIES

The table below contains the minimum set of PRRC responsibilities and the related processes:

PRRC Responsibility	Related SOP(s)
a) Ensuring that the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released.	SOP-202 Manufacturing SOP-305 Supplier handling
b) Ensuring that the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date.	SOP-200 Design and Development Control SOP-303 Change Management
c) Ensuring that the post-market surveillance obligations are complied with in accordance with MDR Article 10(10).	SOP-105 PMS
d) Ensuring that the reporting obligations referred to in MDR Articles 87 to 91 are fulfilled.	SOP-103 Complaint handling SOP-108 Vigilance Reporting
e) Ensuring that in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of MDR Annex XV is issued.	SOP-102 Clinical evaluation

1.7 ADDITIONAL PRRC RESPONSIBILITIES

The table below contains additional PRRC responsibilities.

PRRC Responsibility	Related SOP(s)
f) The PRRC is co-approving the related SOPs in the table above to ensure compliance with the MDR.	SOP-300 Document & records control
g) The PRRC is co-approving the Summary Reports of the Internal Audit Program.	SOP-304 Audit
h) The PRRC is co-approving the Reports of the Management Reviews.	SOP-100 Management

2 REFERENCES

2.1 PROCEDURES, INSTRUCTIONS AND GUIDELINES

[1] SOP-100 Management
[2] SOP 102 Clinical evaluation
[3] SOP-103 Complaint handling
[4] SOP-10 Vigilance Reporting
[5] SOP-105 PMS
[6] SOP-200 Design and Development Control
[7] SOP-202 Manufacturing
[8] SOP-300 Document & records control
[9] SOP-304 Audit
[10] SOP-305 Supplier Handling
[11] MDR 2017 / 745

2.2 TEMPLATES AND FORMS

[12] T-101-12 Appointment PRRC
[13] T-101-13 Appointment PRRC deputy

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Certificate of Completion

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