



Technical Report No. 73-2

Application of Medical Device Regulation Annex I Requirements for Staked Needle Syringes



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1.0 Introduction

The European Union regulation (EU) 2017/745 on medical devices, referred to as MDR, introduces new requirements for manufacturers of medical devices. These new requirements, according to MDR Articles 1(8) and 1(9), subparagraphs 2, also apply to pharmaceutical companies developing and manufacturing combinations of medicinal products and medical devices, including prefilled syringes (PFS), both integral and single integral products. The device part of these PFS must comply with the rules outlined in MDR Annex I: General Safety and Performance Requirements (GSPRs). Evidence of compliance, as described in Article 117, must be provided by requesting an opinion from a Notified Body (NB) appropriately accredited for the issuance of such an opinion **(1)** (See **Section 3.0**).

PDA Technical Report No. 73-2: Application of Medical Device Regulation Annex I Requirements for Staked Needle Syringes represents the current state of knowledge as to its application. As this is a new process based on a new regulatory requirement, expectations of the NBs and competent authorities may diverge as the process evolves. Ultimately, the responsibility for the entire content of the submission file that is reviewed by the NB lies with the applicant. Accordingly, the intended users of TR-73-2 are applicants, i.e., pharmaceutical companies, their suppliers, and other interested parties.

1.1 Purpose

As an addendum to *PDA Technical Report No. 73: Prefilled Syringe User Requirements for Biotechnology Applications*, this technical report provides recommendations on preparing the required documentation of the device part of the PFS to facilitate obtaining an NB opinion.

Table 5.1-1 in **Section 5.0** provides GSPR guidance on the syringe components, syringe subassembly ready for filling, and the device part (see **Figure 4.2-1**). It systematically recommends the amount and depth of information needed for each relevant GSPR to support pharmaceutical companies in assembling the submission file to the NBs.

Section 4.0 provides information on documents that provide guidance on completing the NB submission file. Following *MDR Annex II: Technical Documentation* to complete the submission file for the NBs is recommended; individual sections can be written in more or less detail, at the discretion of the submitting applicant **(2)**. Additional guidance can be found in the Team-NB position papers on documentation requirements and on best practices for the submission of technical documentation **(2,3)**. TR-73-2 also follows the same structure as the submission file.

1.2 Scope

While the scope of PDA TR-73 applies only to 1 ml long glass PFS for biotechnology application, TR-73-2 applies to PFS of glass and polymer of different volumes within the definition of MDR Article 1(9), subparagraph 2. The scope of TR-73-2 is not exclusive for biotechnology applications.

The device part, including its corresponding components and materials, are in scope as they will be evaluated by the NBs, but the medicinal product (drug) is not.

Figure 4.2-1 provides a schematic overview of the drug and the device parts of a PFS and its components; a backstop can be added if needed.