



# WHO template procurement specifications for sterile hypodermic syringes for single use including a reuse-prevention feature \*

8 November 2002

*The syringes will meet ISO standard 7886-1 on sterile hypodermic syringes for single use unless specified otherwise in this document.*

## **Type and application**

- Non-prefilled, single-use syringes for general purpose.
- Including a reuse prevention feature, i.e., a feature that activates after intended use to prevent subsequent reuse of the syringe.<sup>†</sup>

## **Nominal capacity**

1.0 ml, 2.0 ml, 3.0 ml, 5.0 ml or 10 ml.

## **Reuse-prevention feature**

The syringe will include a feature that prevents subsequent reuse.

**a. For syringes that will not allow reconstitution and subsequent injection with the same syringe**, the syringe shall be passively and automatically rendered unusable following completion of its intended use. No secondary or additional action on the part of the user shall be required. The syringe may not be re-filled beyond the limits set for aspiration either by withdrawal of the plunger (<100N) nor by liquid back pressure through the needle (<300kPa) when a full dose of liquid has been delivered.

**b. For syringes that will allow reconstitution and subsequent injection with the same syringe**, it shall be possible to voluntarily inactivate the syringe after completion of its intended use or the syringe shall be passively and automatically rendered unusable following completion of its intended use. After inactivation, the syringe may not be re-filled beyond the limits set for aspiration either by withdrawal of the plunger (<100N) nor by liquid back pressure through the needle (<300kPa).

## **Resistance to shock and shipping**

There shall be no effect on the performance of the syringe after it has been dropped in its single unit packaging from a height of one metre onto a concrete surface. In addition, there will be no effect on the performance of the syringe when tested in accordance with ASTM D

\* Auto-disable syringes for immunization are excluded from these specifications.

<sup>†</sup> Syringes designed to reduce the risk of needlestick injuries may also comply with the present specifications with regard to their reuse prevention feature. However, anti-needlestick properties of syringes are not in themselves addressed in these specifications.

99/01 and ASTM D/5276/98. This means no premature activation of the reuse-prevention feature or any other damage that could affect the safe use of the product.

### ***Needle***

The syringe will have an integrated needle or non-integrated needle.

- **For syringes with integrated needle:** fixed needle should have a minimum needle union force applied as pull in the direction of the needle axis in accordance with ISO 7864:1993.
- **For syringes with non-integrated needle:** once fixed, the needle cannot be removed again and should become an integral part of the syringe.

### ***Bubble exclusion***

Excessive air bubbles introduced during filling will be easily moved to the top of the barrel by flicking the finger-nail against the barrel and then expelled by depressing the plunger.

### ***Aspiration for blood***

When the syringe is filled with liquid to the maximum graduated capacity, sufficient flexibility will be provided to enable the plunger to be withdrawn sufficiently to check for the presence of blood. Aspiration will be possible at any position of the plunger within the graduated range.