EU Declaration of Conformity for Medical Devices

According to REGULATION (EU) 2017/745 on Medical Devices

Cetro Medical AB
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Sweden
www.cetromedical.se
SRN: SE-MF-000012172

Basic UDI: 73401943961SE5

961S Amniotic membrane perforator – STERILE

Article number: *9601*

Intended purpose: The product is a single use, sterile device, used by healthcare personnel for opening the amnion at childbirth, in cases where artificial rupture of the membranes is required.

Medical device classification: Class IIa / Rule 6 (according to Annex VIII)

This EU declaration of conformity is issued under the sole responsibility of Cetro Medical AB.

The device covered by this declaration is in conformity with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Conformity assessment procedure: Annex I, II, III, IX, Article 19 and Annex IV

Notified Body: NB 3033 RISE Medical Notified Body AB

Smålandsstenar, Sweden

2025-09-16

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