Medicines & Healthcare products Regulatory Agency

DEVICE SAFETY INFORMATION (DSI)

Devices supplied without valid UKCA/CE conformity markings or certification: remove from use and place in quarantine (DSI/2026/007)

Specialisms: *General practice, General surgery, Pathology, Haematology and oncology, Theatre practitioners, Emergency medicine, Dentistry, Infection prevention, Pharmacy*

DEVICE DETAILS

Device	Manufacturer
VAKU-8 Blood Collection / Infusion / Scalp Vein Set	Hindustan Syringes & Medical Devices Ltd
Bipson's Gauze Swab Sterile	Bipson Surgical Private Ltd
Technocut Scalpel	HMD Healthcare India Pvt. Ltd., (Formerly Niraj Industries Pvt Ltd.,)
Romsons Alco Swabs	Romsons Group Private Ltd
Medi Grip Adhesive Bandage (Antiseptic)	Precision Coatings (P) Ltd
Bone Marrow Biopsy Needle	Meditech Devices Pvt. Ltd.

AFFECTED LOT SERIAL NUMBERS

All

MANUFACTURED BY

Multiple manufacturers (see Device Details section).

Summary

The MHRA has become aware of a number of medical devices being supplied on the UK market that do not comply with the requirements of the UK Medical Device Regulations 2002 (UK MDR 2002) or with the EU Medical Devices Regulation (EU) 2017/745 (EU MDR). While the MHRA has not identified a specific defect or safety concern associated

with these products, they do not meet the regulatory requirements for supply on the UK market, meaning assurance regarding their safety, sterility and performance cannot be fully guaranteed. The affected devices may be used in a variety of clinical settings, including blood collection and infusion, surgical procedures, biopsy procedures, wound management and skin preparation/ disinfection.

Advice for Healthcare Professionals:

- review whether your organisation holds, uses or supplies any of the devices listed in this DSI
- immediately stop using and supplying any identified product(s) and quarantine all remaining stock
- identify and use alternative compliant products
- retain affected devices pending further advice from the MHRA
- alert the MHRA that you are in possession of an affected device via devices.compliance@mhra.gov.uk quoting the DSI reference number (DSI/2026/007)
- providers should ensure all relevant members of staff receive this Device Safety Information (DSI) and that they understand the problem and actions to be taken
- report any suspected or actual adverse incidents involving these devices. There are specific reporting arrangements for healthcare professionals to follow in each region
- healthcare professionals should report incidents:
    - in England and Wales to the Yellow Card scheme or via the Yellow Card app
    - in Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system
    - in Northern Ireland to the Yellow Card website in accordance with your organisations medical device policies and procedures

Advice for Healthcare Professionals to Provide to Patients:

- there is no advice for healthcare professionals to provide to patients regarding this DSI

Advice for Distributors:

- identify any affected devices within your possession or control
- cease further supply of affected devices
- notify the MHRA immediately via devices.compliance@mhra.gov.uk if you think you have received, supplied or distributed any affected devices, and provide details of any onward distribution where known and quote the DSI reference number (DSI/2026/007)

- assist the MHRA with traceability activities where requested
- maintain records of customers supplied with affected devices
- inform customers who may have received affected stock

Explanation of identified safety issue

The MHRA has become aware of a number of medical devices being supplied in the UK market which do not comply with the applicable UK medical device regulatory requirements. These devices and their manufacturers are listed above.

The MHRA has not identified a specific device defect, performance issue or safety signal associated with these products. However, without legitimate UKCA or CE device certification required for supply on the UK market, assurance regarding conformity assessment, quality management systems, safety, sterility and performance cannot be fully guaranteed.

Reporting advice

Healthcare professionals should report incidents:

- in England and Wales to the Yellow Card website or via the Yellow Card app
- in Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system
- in Northern Ireland to the Yellow Card website in accordance with your organisations medical device policies and procedures

Additional information:

You can sign up to receive email updates on alerts and device safety information from the MHRA.

You can sign up to receive our monthly roundup of safety communications.

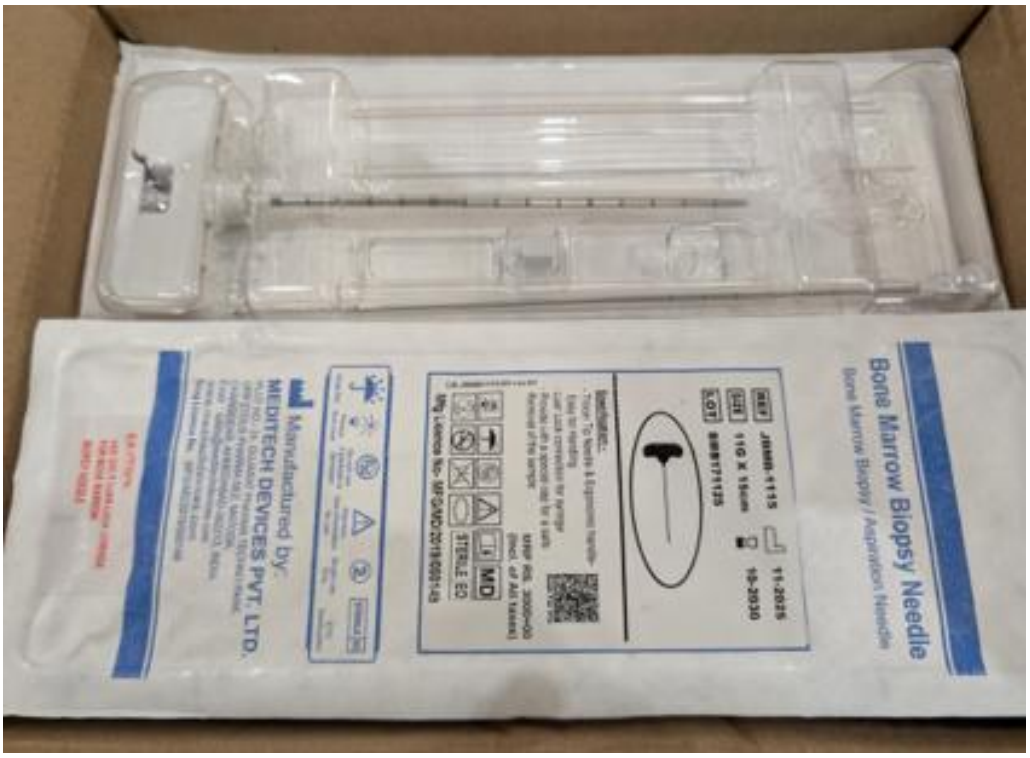
For any enquiries, please contact info@mhra.gov.uk

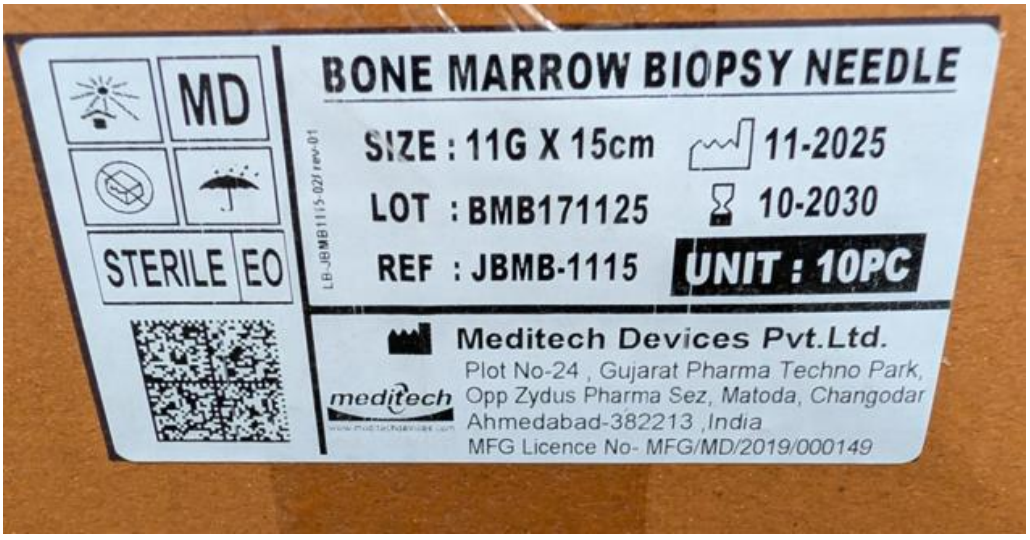
Stakeholder engagement:

- Incident Reporting & Investigation Centre (IRIC) for Scotland
- NHS Wales
- NHS England Patient Safety Team
- NI Health Estates Directorate
- Medical Device Safety Officers (MDSOs)

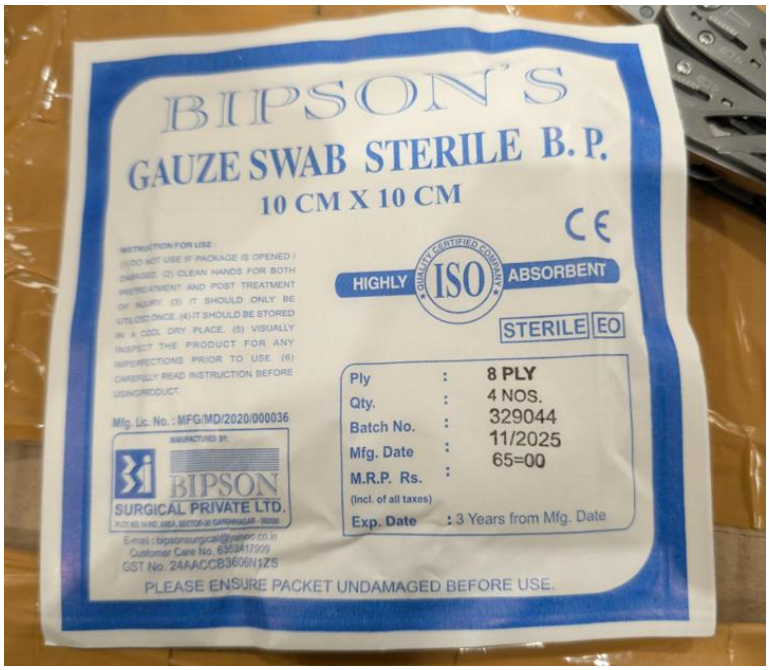
Annex 1: Images of the Devices Identified

Meditech Devices Pvt. Ltd. Bone Marrow Biopsy Needle



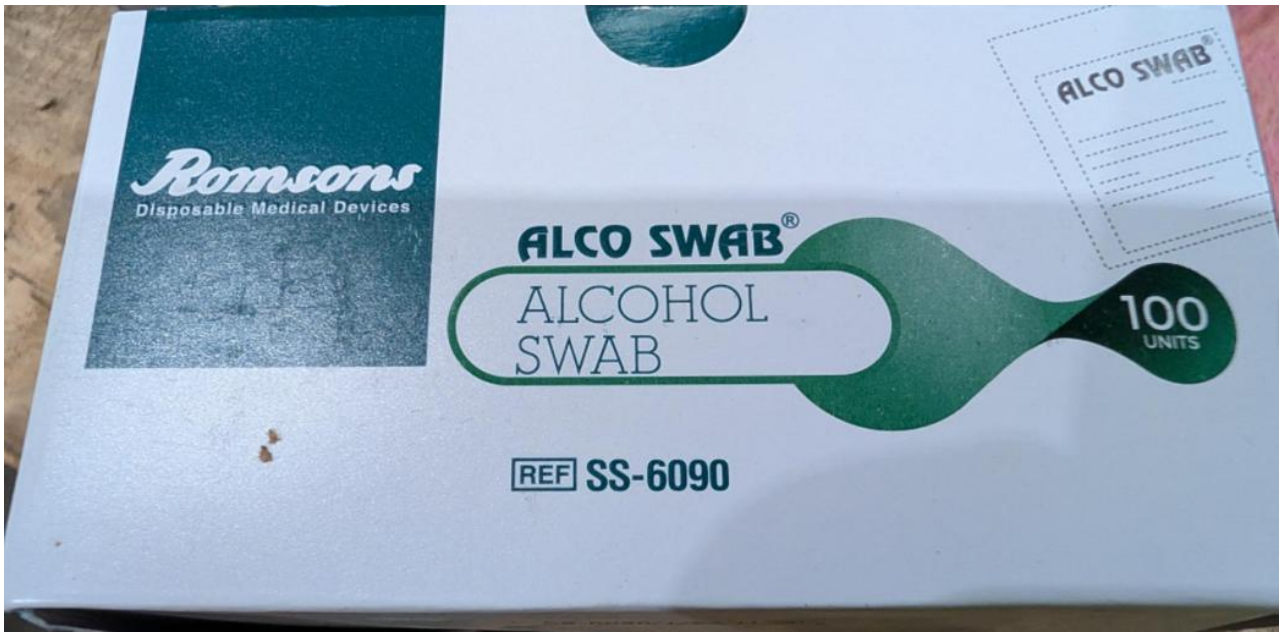


Bipson Surgical Private Ltd Gauze Swab Sterile



Precision Coatings (P) Ltd Medi Grip Adhesive Bandage (Antiseptic)

Romsons Group Private Ltd Alco Swab



Niraj Industries Ltd Technocut Scalpel

Hindustan Syringes & Medical Devices Ltd VAKU-8 Blood Collection/ infusion/ scalp vein set


VAKU-8
HINDUSTAN SYRINGES & MEDICAL DEVICES LTD.
21X3/4
0.80X19mm.
VOL. 0.29 ml
MFG. : OCT-2025
EXP. : SEP-2028