Rev 1: September 2018

FSN Ref: NX001 FSCA Ref: 001

Date: 06JUL2023

Urgent Field Safety Notice
NxtGen Infant Transport Incubator

For Attention of*:Hospital Neonatal Transport Staff

Contact details of local representative (name, e-mail, telephone, address etc.)*
International Biomedical AG Glütschbachstrasse 100 CH-3661Uetendorf, Switzerland +41.33.345.66.00 welcome@int-bio.ch

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Urgent Field Safety Notice (FSN)
NxtGen Infant Transport Incubator
Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	NxtGen infant transport incubator – equipment used to aid with moving neonatal infants between hospitals or within a hospital in an enclosed warm environment
1.	2. Commercial name(s)
	NxtGen
1.	3. Unique Device Identifier(s) (UDI-DI)
	00850018561013
1.	4. Primary clinical purpose of device(s)*
	The NxtGen Transport Incubator is intended for use by personnel trained in neonatal care to facilitate the movements of neonates by air or ambulance. The transport incubator provides heat in a controlled manner to neonates through an enclosed temperature controlled environment. The transport incubator is also intended to carry equipment designed for airway management and monitoring of the neonatal infant's status.
1.	5. Device Model/Catalogue/part number(s)*
	NxtGen; 732-0000
1.	6. Software version
	Only where relevant.
1.	7. Affected serial or lot number range
	NX100 – NX160
1.	8. Associated devices
	N/A

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	The device does not have a valid CE certificate associated with it. The device has been cleared for sale/patient use in the US under the 510k program and in Canada with a Health Canada License. The CE application with BSI, the manufacturer's notified body has been delayed due to the transition to the MDR. Device labelling incorrectly contains a CE mark that needs to be removed.
2.	2. Hazard giving rise to the FSCA*
	Device has been in use for 2 years with no reported incidents. While the CE mark has not been granted for this device, the application continues to be under review. Clinical effectiveness has not been substantiated in the EU as part of the CE application though it has been substantiated in other countries and regions.
2.	3. Probability of problem arising
	N/A
2.	4. Predicted risk to patient/users
	No patient harm determined.
2.	5. Further information to help characterise the problem
	N/A
2	6. Background on Issue

.	Device has been in use for 2 years with no reported incidents. While the CE mark has not been granted for this device, the application continues to be under review. Clinical effectiveness has not been substantiated in the EU as part of the CE application though it has been substantiated in other countries and regions.
2	7. Other information relevant to FSCA
.	The manufacture encourages the hospitals to not remove the device from use due to the urgent need for transport incubators. While the device does not have a valid CE mark, the device has proven to be safe and effective in protecting delicate neonates during transport within and between hospitals.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☒ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other ☐ None IBAG will coordinate with hospital to replace device identification labelling at user facility. Continue using device.	
3.	2. By when should the action be completed?	October 1, 2023
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. Provide further details of patient-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None Removal of CE mark from device identification label	
3	6. By when should the action be completed?	October 1, 2023
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay	

	user in a patient/lay or non-professional user information letter/sheet?
	Choose an item. Choose an item.

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**International Biomedical**
	b. Address	**8206 Cross Park Drive, Austin, TX 78754 USA**
	c. Website address	**www.int-bio.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	**N/A**
4.	10. Name/Signature	**Amy Pieper** **Director of Regulatory Affairs** 

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.