Batch Recall

Product name		
Reference	***Designation***	***Batch***
BBOVNS60	BBCOM Electrode paediatric	22053198 22043165 22033120 22033119 22043150 22013067 22043161 22013066 21112941 21112940 21123004 21082859 21102892 21072815 21082848
3RC20NS60	PRECOM Electrode paediatric	22033127 22013073 21123010 22033108 21112958 21082856 21102889
3RC30NS60	PRECOM Electrode paediatric	22053194 22013058 21123011 21112959 21102890 21082857

Product name		
Reference	***Designation***	***Batch***
301202035	PRECOM Electrode paediatric	22043140 22013062 22033115 21123014 21112963 21082864 21102898 21072823
301303009	PRECOM Electrode	22033113 22013060 21123016 21112967 21102902 21082854
301303035	PRECOM Electrode paediatric	22033112 22013059 21123009 21112957 21102888 21082855
BBOV0435	BBCOM Electrode paediatric	22013074 22043158 21112939 21102909
BBOVPMNS	BBCOM Electrode paediatric	22043151 21123005 21112942 21082860 21102893 21072816

22/09/2022,

Dear Materialovigilance Correspondent or Facility Director,

Comepa is immediately recalling from the market the BBCOM Electrodes and PRECOM Electrodes devices.

The National Agency for the Safety of Medicines and Health Products has been informed of this recall on 22/09/2022.

Please stop using these devices immediately and quarantine them to prevent inadvertent use. If you have BBCOM Electrodes and PRECOM Electrodes on deposit, your Comepa representative will contact you to arrange the return of the affected devices.

Reason for withdrawal: Electrode detaches from conductive gel

Please share this information within your Operating Room and relevant departments, and any other function in your facility that needs to be aware of this corrective safety action.

When this letter is sent to a center that has BBCOM and PRECOM electrodes in stock, we ask the material vigilance correspondent to use the attached questionnaire in order to verify that all the stock present in the establishment has been returned. The questionnaire must be completed and returned to Comepa by email at **sarah.raveau@comepa.com** and **fadela.guendouzi@comepa.com**.

It is also important for you to keep track of all actions you take regarding this recall.

We apologize for any inconvenience this action may cause you, but we believe it is necessary to ensure the best possible patient care. If you have any questions, please do not hesitate to call your sales representative.

Best regards,

Ms. Fadela Guendouzi

Quality Assurance Manager Regulatory Affairs

Acknowledgement of receipt and customer response form

Please complete and return this form by email to

sarah.raveau@comepa.com and fadela.guendouzi@comepa.com

Name of hospital	
Name, Surname :	
Function :	
Address :	
Phone :	
Email :	

We certify that we have recalled the batches from all users of our health care facility.

Reference :

If you have any, number of products removed : _____

Date and signature :