Belmont INSTRUMENT LLC

Together, Saving Lives.

VOLUNTARY Medical Device Recall
Certain lots of buddy™ Disposable Set

September 21, 2018

Dear Belmont Distributor,

cc: Chairman Medical Board and Relevant Head of Departments of affected Hospitals/Clinics:

The purpose of this letter is to advise you that Belmont Instrument LLC is voluntarily recalling buddy™ Disposable Set, Part No. 905-00010(P), with the following lot numbers:

2018-05 01 (expiry 2021-05-31)
2018-07 05 (expiry 2021-07-31)
2018-08 03 (expiry 2012-08-31)

The buddy™ Disposable Set, Part No. 905-00010(P), is used with the Belmont® buddy™, buddy™ 2, buddy lite™, buddy lite™ AC, and buddy plus™ for the administration of warmed blood, blood products, and intravenous solution in clinical settings. According to our records, your organization purchased and received one or more of the affected lots, which were manufactured between May 2018 and August 2018. These disposable sets were manufactured using a material that was in the process of being qualified and were released prematurely. Please note that the in-process and final testing results show that these sets should perform as expected, and the company has received no complaints associated with these lots. We have performed a health hazard evaluation and determined that there is very low biocompatibility risk to the patient from use of the disposable set, however, out of an abundance of caution, Belmont is voluntarily recalling these lots of buddy™ Disposable Sets.

We kindly ask that you immediately discontinue use of any affected lots and destroy these materials. No other lots of buddy™ disposables have been impacted by this issue. Please ensure the appropriate staff is made aware of this notice. Distributors, please note that you are required to include a list of all affected end-users that are provided with a copy of this recall letter.

Please confirm receipt of this notice and the actions described by completing the attached Acknowledgement Form and returning it via email to regulatory@belmontinstrument.com.

Once we receive your return response, we will coordinate the appropriate credit to your account. We appreciate your immediate attention to this matter and apologize for any inconvenience this may have caused.

If you have further questions regarding this recall, please contact me at 978-696-9204, or by email at regulatory@belmontinstrument.com.

Sincerely,

[redacted]

Dori A. Koza
Director Regulatory Affairs & Quality Assurance

ACKNOWLEDGMENT AND RECEIPT FORM

Voluntary Medical Device Recall: buddy™ Disposable Set

RESPONSE IS REQUIRED

Please print the following information:

Facility Name:				Contact Person:	
Address:				Title:	
City:				Email:	
State:		Zip:		Phone:	

Are you a:

☐ Distributor

☐ Healthcare Facility

☐ Military

☐ Other If "Other", please describe: _____

Please indicate how many affected sets were in stock and destroyed: _____

DISTRIBUTORS ONLY – Please check all that apply:

☐ All facilities or customers to which we have distributed the affected product have been notified by providing a copy of the letter and this recall return response form.

☐ A list of affected end-users is attached.

Please indicate how many sets were sold: _____

I confirm that I have read and understand the instructions provided in the September 20, 2018 recall notice, and have destroyed any affected lots of buddy™ disposables.

Signature _____