

Approved By:

[\(CO-266\) DCP-004: IFU updates for Needle Sets and Flow controllers](#)

Description

The following IFU artwork documents were updated: ***AS-0010003 - Updated Emergo Address. Changed recommended internal pressure units from mmHg (kPa) to psi (bar) for Portuguese (PT-BR). Changed priming volume specification for Italian. Changed "ml" to "mL". Added storing temperature range in Fahrenheit units. Corrected text and steps numbers referred in the step 19 of the Instructions for Use table in Serbian (SR). Corrected text in the step 20 of the Instructions for Use table in Serbian (SR). Updated glossary to meet EU MDR Labeling per DCP-004. ***AS-0010347 - Updated Emergo Address. ***AS-0010281 - Updated Emergo Address. Added translations PL, NL, EL and CS. Changed recommended internal pressure units from mmHg (kPa) to psi (bar) for Portuguese (PT-BR). Changed "ml" to "mL". Added storing temperature range in Fahrenheit units. Corrected steps numbers referred in the step 19 of the Instructions for Use table in Serbian (SR). Updated glossary to meet EU MDR Labeling per DCP-004. ***AS-0010011 - Updated Emergo Address. Changed recommended internal pressure units from mmHg (kPa) to psi (bar) for Portuguese (PT-BR). Changed "ml" to "mL". Added storing temperature range in Fahrenheit units. Updated glossary to meet EU MDR Labeling per DCP-004. ***AS-0010044 - Updated Emergo Address. Updated description in Turkish. Changed recommended internal pressure units from mmHg (kPa) to psi (bar) for Portuguese (PT-BR). Added storing temperature range in Fahrenheit units. Updated glossary to meet EU MDR Labeling per DCP-004. ***AS-0010169 - Updated Emergo Address. Updated position of header elements and added the REF number. Added/updated translations PT-BR, SR, PL, NL, EL and CS. Changed "ml" to "mL". Added storing temperature range in Fahrenheit units. Changed "ml/hr" to "mL/h". Changed wording of the NOTE associated with the Performance table for English (EN). Updated glossary to meet EU MDR Labeling per DCP-004. ***AS-0010040 - Updated Emergo Address. Added/updated translations PT-BR, SR, PL, NL, EL and CS. Changed "ml" to "mL". Added storing temperature range in Fahrenheit units. Changed "ml/hr" to "mL/h". Changed wording of the NOTE associated with the Performance table for English (EN). Updated glossary to meet EU MDR Labeling per DCP-004. ***AS-0010380 - Updated glossary to meet EU MDR Labeling per DCP-004. Updated position of header elements and added the REF numbers. Changed "ml" to "mL". ***AS-0010041 - Updated Emergo Address. Updated position of header elements and added the REF number. Added/updated translations PT-BR, TR, SR, PL, NL, EL and CS. Changed wording of the NOTE associated with the Performance table for English (EN). Updated glossary to meet EU MDR Labeling per DCP-004. The following affected Material Specification documents were updated accordingly: ***MS-0010362, MS-0010361 and MS-0010363 - Specification 1.1: Changed material size from 17"x22" to 21"x21". Specification 1.2: Updated artwork document to version 2. Specification 1.6: Changed finished size from 5.5"x8.5" to 5.25"x5.25". ***MS-0010364 - Specification 1.2: Updated artwork document to version 2. ***MS-0010365 - Specification 1.2: Updated artwork document to version 3. ***MS-0010347 - Transferred previous document version content to FRM-048 and added new information in sections 1.4, 1.8, and 1.9. Specification 1.1: Changed material size from 11"x17" to 17"x22". Specification 1.2: Updated artwork document to version 4. ***MS-0010346 - Specification 1.1: Changed material size from 11"x17" to 17"x22". Specification 1.2: Updated artwork document to version 5. ***MS-0010354 - Specification 1.5: Updated artwork document to version 4. ***MS-0010345 - Transferred previous document version content to FRM-048 and added new information in sections 1.4, 1.8, and 1.9. Specification 1.1: Changed material size from 11"x17" to 17"x22". Specification 1.2: Updated artwork document to version 5.

Justification

Required IFU artwork document and Material Specification documents updates per approved design change plan, DCP-004. This CO is one of many related to DCP-004. Product BOMs affected by this change order will be updated on separate change orders to manage the number of documents in each CO during review.

Assigned To:	Initiated By:	Priority:	Impact:
Luis Bojorquez	Luis Bojorquez	High	Major

Version History:

Author	Effective Date	CO#	Ver.	Status
Travis Schraeder	August 22, 2023 11:09 AM PDT	CO-266	2	Published
Travis Schraeder	April 29, 2022 4:19 PM PDT	CO-27	1	Superseded
Ivan Gutierrez	March 17, 2022 2:36 PM PDT	CO-12	0	Superseded