

<u>Version</u>	<u>Description</u>	<u>Author</u>	<u>Date</u>
<u>A</u>	Updated to SAP, Removed the neonate cuffs and FlexiPort Cuffs from DoC. Removed component parts that are not accessories and not supported in the technical file or compliant with MDD labeling.	S. Schmidt	2011-01-07
<u>B</u>	Updated to new format. Updated EU REP address, removed Notified Body since this is a class I product.	S. Schmidt	2011-08-12
<u>C</u>	Added annex for Saudi Arabia submission. Updated to new format. Removed bladders, since these are components and are not CE marked (all 5089-X numbers and 5200-04, 05, 06, and 11, checked pkg labels). Added 4500-01, 4500-200, 5082-21H, 5082-64, 5082-65, 5200-01, 5200-02, 5200-03, 5200-10 (checked all pkg labels include CE mark). Added 2-pc cuffs being transferred from Jungingen to Tijuana.	S. Schmidt	2012-01-10
<u>D</u>	1) Added EN/ISO 81060-1 2) Removed EN 1060-1 and EN 1060-2 since both are formally withdrawn as of May 31, 2015 and all listed cuffs have met EN/ISO 81060-1 (see 60066583) which is in force. 3) Corrected UMDNS code 11072 to identify device name and not definition 4) Operations provided listed "#" numbers that correlate to device numbers listed within test report 60066583. 5) Updated table in annex as a duplicate of the table within the DoC.	J. Strong	2015-05-21
<u>E</u>	Since cuffs (no bladder) are CE marked for the entire device (cuff & bladder), the following cuffs (no bladder) material numbers are being added back onto this DoC: 5082-01, 5082-01H, 5082-02, 5082-11, 5082-16, 5082-21, 5082-24. Since descriptions have been included in table in the main declaration of conformity, the table in the annex isn't needed, so that data has been removed.	M. McGovern	2016-01-08
<u>F</u>	Updated for MDR	C. Lefancheck	2020-03-23
<u>G</u>	Class I updates for MDR	C. Lefancheck	2021-06-15
<u>H</u>	DoC Correction & SRN	K. Love	2021-08-20
<u>J</u>	DoC Correction, New SAP Change Number	K. Love	2021-08-23

K	Updated to new template, added SRN for Skaneateles and updated the part number list to a table format.	K. Ockenfels	2021-10-12
L	Updated to new template, added Intended Purpose Statement	K. Love	2021-11-08
M	Updated part list to remove the -SC cuffs which are now classified as Kits due to small bore compliance	K Ockenfels	2022-02-04
N	Add EN ISO 14971:2019, EN ISO 20417:2021. Update DoC expiration date to align with EN ISO 13485 certificate.	K. Love	2022-12-02
P	Added product description for all listed product codes	M. Solanki	2024-05-10
R	Updated the list – SC cuff as per Rev M, SC cuffs no longer selling in EU Region, SC cuff invertedly added	M. Solanki	2024-06-12
S	Updating Hill-Rom to Baxter DoC template	M. Solanki	2024-12-11