Qualifications summary

DPTE-BetaBag® 190 PE/EVOH/PE 10L – 30L – 100L – 150L non-sterile, empty, with innerchute

CRCA 2018-001 | 001

GETINGE

Document description

Equipment:	**DPTE-BetaBag® 190 PE/EVOH/PE 10L – 30L – 100L – 150L non-sterile, empty, with innerchute**		
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Version history

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25/10/2018	000	First issue	V. Leman
01/02/2019	001	Modifications apportées aux tests n° 2, 7, 11, 18 et 27	V. Leman

Signatories

Date	Rédacteur	Vérificateur	Approbateur
01/02/2019	V. Leman	M. Janez	M. Janez

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1. DPTE-BetaBag® 190 PE/EVOH/PE qualification

TEST N°	DESCRIPTION	ACCEPTANCE CRITERIA	RESULTS
DPTE-BetaBag® Before Gamma Irradiation			
1	Operations with the DPTE®	• Connection of Beta part is possible • Alpha part opens once beta part is connected • Disconnecting of beta part with alpha part open impossible • Alpha part cannot be opened with beta door missing • Disconnection of Beta part is possible	CONFORM
	Operation's simulation	The transfer of components is possible and easy	CONFORM
2	Leaktightness of the DPTE® Beta	According Getinge Specification	CONFORM
3	Leaktightness between Beta Flange and Alpha Flange	According Getinge Specification	CONFORM
	Leaktightness between Beta Door and Alpha Door	According Getinge Specification	CONFORM
4	Leaktightness of the Bag	According Getinge Specification	CONFORM
DPTE-BetaBag® After Gamma Irradiation			
5	Operations with the DPTE®	• Connection of Beta part is possible • Alpha part opens once beta part is connected • Disconnecting of beta part with alpha part open impossible • Alpha part cannot be opened with beta door missing • Disconnection of Beta part is possible	CONFORM
	Operation's simulation	The transfer of components is possible and easy	CONFORM
6	Connection resistance Alpha-Beta	According Getinge Specification	CONFORM
	Connection resistance Beta door – Beta flange	According Getinge Specification	CONFORM
7	Leaktightness of the DPTE® Beta	According Getinge Specification	CONFORM
8	Leaktightness of the Bag	According Getinge Specification	CONFORM

TEST N°	DESCRIPTION	ACCEPTANCE CRITERIA	RESULTS
DPTE-BetaBag® After Gamma Irradiation and After 5 connections/disconnections			
9	Operations with the DPTE®	• Connection of Beta part is possible • Alpha part opens once beta part is connected • Disconnecting of beta part with alpha part open impossible • Alpha part cannot be opened with beta door missing • Disconnection of Beta part is possible	CONFORM
	Operation's simulation	The transfer of components is possible and easy	CONFORM
10	Connection resistance Alpha-Beta	According Getinge Specification	CONFORM
	Connection resistance Beta door – Beta flange	According Getinge Specification	CONFORM
11	Leaktightness of the DPTE® Beta	According Getinge Specification	CONFORM
12	Leaktightness between Beta Flange and Alpha Flange	According Getinge Specification	CONFORM
	Leaktightness between Beta Door and Alpha Door	According Getinge Specification	CONFORM
13	Flange/Bag Welding resistance	≥ 15 N/15 mm	CONFORM
14	Bag sealing strength	≥ 15 N/15 mm	CONFORM

CONCLUSION

All the tests of the qualification were performed. The performances of the DPTE-BetaBag® 190 PE/EVOH/PE are in accordance with GETINGE specifications.

Bioburden analyses are done during dose audit (according ISO 11137 and ISO 11737) and are in accordance with GETINGE specifications.

Endotoxin analyses are done before and after gamma irradiation and are in accordance with Getinge specifications.

2. DPTE-BetaBag® 190 PE/EVOH/PE SHELF LIFE T0+ 24 months

TEST N°	DESCRIPTION	ACCEPTANCE CRITERIA	RESULTS
DPTE-BetaBag® Before Gamma Irradiation			
15	Operations with the DPTE®	• Connection of Beta part is possible • Alpha part opens once beta part is connected • Disconnecting of beta part with alpha part open impossible • Alpha part cannot be opened with beta door missing • Disconnection of Beta part is possible	CONFORM
	Operation's simulation	The transfer of components is possible and easy	CONFORM
16	Connection resistance Alpha-Beta	According Getinge Specification	CONFORM
17	Connection resistance Beta door – Beta flange	According Getinge Specification	CONFORM
18	Leaktightness of the DPTE® Beta	According Getinge Specification	CONFORM
19	Leaktightness of the Bag	According Getinge Specification	CONFORM
20	Flange/Bag Welding resistance	≥ 15 N/15 mm	CONFORM
21	Bag sealing strength	≥ 15 N/15 mm	CONFORM
22	Leaktightness between Beta Flange and Alpha Flange	According Getinge Specification	CONFORM
23	Leaktightness between Beta Door and Alpha Door	According Getinge Specification	CONFORM
DPTE-BetaBag® After Gamma Irradiation			
24	Operations with the DPTE®	• Connection of Beta part is possible • Alpha part opens once beta part is connected • Disconnecting of beta part with alpha part open impossible • Alpha part cannot be opened with beta door missing • Disconnection of Beta part is possible	CONFORM
	Operation's simulation	The transfer of components is possible and easy	CONFORM
25	Connection resistance Alpha-Beta	According Getinge Specification	CONFORM
26	Connection resistance Beta door – Beta flange	According Getinge Specification	CONFORM
27	Leaktightness of the DPTE® Beta	According Getinge Specification	CONFORM

TEST N°	DESCRIPTION	ACCEPTANCE CRITERIA	RESULTS
28	Leaktightness of the Bag	According Getinge Specification	CONFORM
29	Flange/Bag Welding resistance	≥ 15 N/15 mm	CONFORM
30	Bag sealing strength	≥ 15 N/15 mm	CONFORM
31	Leaktightness between Beta Flange and Alpha Flange	According Getinge Specification	CONFORM
32	Leaktightness between Beta Door and Alpha Door	According Getinge Specification	CONFORM
33	Particle level	According Getinge Specification	CONFORM

CONCLUSION

At T0 + 24 months, the performances of the DPTE-BetaBag® 190 PE/EVOH/PE are in accordance with GETINGE specifications.

GETINGE

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