Qualifications summary

6007001904 – DPTE-BetaBag® 105 PE/EVOH/PE 30L non sterile, empty, with inner sleeve, open bottom side

CRCA 2020-009 | 000

GETINGE

Document description

Equipment:	**6007001904 – DPTE-BetaBag® 105 PE/EVOH/PE 30L non sterile, empty, with inner sleeve, open bottom side.**		
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17/12/2020	000	First issue	V. Leman

Signatories

Date	Prepared by	Reviewed by	Approved by
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1. DPTE-BetaBag® 105 PE/EVOH/PE qualification

TEST N°	DESCRIPTION	METHOD	ACCEPTANCE CRITERIA	RESULTS
DPTE-BetaBag® Before Gamma irradiation				
1	Operations with the DPTE®	NA	• 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
2	Leaktightness between Beta Flange and Alpha Flange	Ammonia leak test	According Getinge Specification	CONFORM
3	Leaktightness between Beta Door and Alpha Door	Ammonia leak test	According Getinge Specification	CONFORM
4	Connection resistance Alpha-Beta	Dynamometric test	According Getinge Specification	CONFORM
5	Connection resistance Beta door – Beta flange	Dynamometric test	According Getinge Specification	CONFORM
6	Leaktightness of the DPTE® Beta	Pressure drop	According Getinge Specification	CONFORM
7	Leaktightness of the bag	Pressure drop	According Getinge Specification	CONFORM
8	Flange / bag sealing strength	Tensile test	≥ 15 N/15 mm	CONFORM
9	Bag sealing strength	Tensile test	≥ 15 N/15 mm	CONFORM

TEST N°	DESCRIPTION	METHOD	ACCEPTANCE CRITERIA	RESULTS
DPTE-BetaBag® After Gamma irradiation				
10	Operations with the DPTE®	NA	• 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
11	Leaktightness between Beta Flange and Alpha Flange	Ammonia leak test	According Getinge Specification	CONFORM
12	Leaktightness between Beta Door and Alpha Door	Ammonia leak test	According Getinge Specification	CONFORM
13	Connection resistance Alpha-Beta	Dynamometric test	According Getinge Specification	CONFORM
14	Connection resistance Beta door – Beta flange	Dynamometric test	According Getinge Specification	CONFORM
15	Leaktightness of the DPTE® Beta	Pressure drop	According Getinge Specification	CONFORM
16	Leaktightness of the bag	Pressure drop	According Getinge Specification	CONFORM
17	Flange / bag sealing strength	Tensile test	≥ 15 N/15 mm	CONFORM
18	Bag sealing strength	Tensile test	≥ 15 N/15 mm	CONFORM

CONCLUSION

All the tests of the qualification were performed. The performances of the DPTE-BetaBag® 105 PE/EVOH/PE are in accordance with GETINGE specifications.

2. DPTE-BetaBag® 105 PE/EVOH/PE real time SHELF LIFE T0+ 30 months

TEST N°	DESCRIPTION	METHOD	ACCEPTANCE CRITERIA	RESULTS
DPTE-BetaBag® Before Gamma irradiation				
19	Leaktightness of the DPTE® Beta	Pressure drop	According Getinge Specification	CONFORM
20	Flange/bag Welding resistance	Tensile test	≥ 15 N/15 mm	CONFORM
21	Bag sealing strength	Tensile test	≥ 15 N/15 mm	CONFORM
22	Operations with the DPTE®	NA	• 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
23	Connection resistance Alpha-Beta	Dynamometric test	According Getinge Specification	CONFORM
24	Connection resistance Beta door – Beta flange	Dynamometric test	According Getinge Specification	CONFORM
DPTE-BetaBag® After Gamma irradiation				
25	Leaktightness of the DPTE® Beta	Pressure drop	According Getinge Specification	CONFORM
26	Flange/bag Welding resistance	Tensile test	≥ 15 N/15 mm	CONFORM
27	Bag sealing strength	Tensile test	≥ 15 N/15 mm	CONFORM
28	Operations with the DPTE®	NA	• 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
29	Connection resistance Alpha-Beta	Dynamometric test	According Getinge Specification	CONFORM
30	Connection resistance Beta door – Beta flange	Dynamometric test	According Getinge Specification	CONFORM

CONCLUSION

At T0 + 30 months the performances of the DPTE-BetaBag® 105 PE/EVOH/PE are in accordance with GETINGE specifications.

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