



Cover Page

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Title Design Validation of the Malta Design Owned Access Codes: Irrigation Sets		
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APPROVALS	
Role	Signature/Date
Roberta M Vassallo Author	See Electronic Signature
Malcolm Zammit Product Design Owner	See Electronic Signature
Nicole Borg Quality Representative	See Electronic Signature
Shannon Kayler Global Medical Affairs	See Electronic Signature

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1. PURPOSE


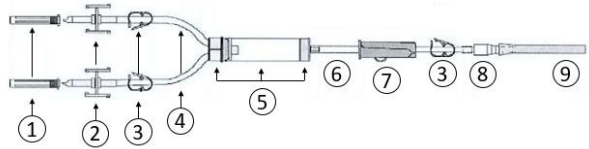
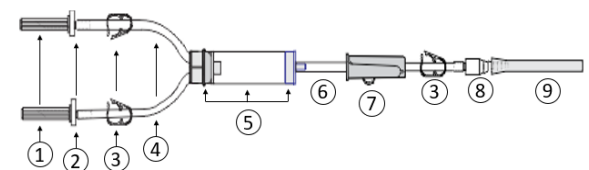
The purpose of this report is to describe the design validation of irrigation sets, the design of which forms part of the Malta Access Products Portfolio. Validation of the products in scope against User Needs and Intended Uses (UNIU) is established through the following:

- A clinical evaluation report is available for these product codes.
- A design validation on similar products has been successfully performed.
- Therapy simulation testing was carried out on representative codes of this product family.

2. SCOPE

The scope of this study includes validation of the UNIU applicable to the irrigation sets (Table 1). These sets are intended to administer irrigation solution from the solution container to the irrigation site and/or surgical sterile field.

Table 1: Irrigation sets to be validated

DHF: Irrigation sets	
<p>7400009A</p> 	<p>Components:</p> <p>1: Protective Cap 2: Spike with Hook 4: Manual Asbl Urology Chamber 6: Roller Clamp 7: Catheter Adaptor 8: Silicone Tube 3: Tube (L=100mm) 5: Tube (L=1753mm)</p>
<p>7401010A</p> 	<p>Components:</p> <p>1: Protective Cap 2: Spike with Hook 3: Large Medical Clamp 5: Manual asbl urology chamber 7: Roller clamp 8: Catheter Adaptor 9: Silicone Tube 4: Tube (L=320mm) 6: Tube (L=1524mm)</p>
<p>E5MC4007N</p> 	<p>Components:</p> <p>1: Protective Cap 2: Spike 3: Large Medical Clamp 5: Manual asbl urology chamber 7: Roller Clamp 8: Catheter Adaptor 9: Silicone Tube 4: Tube (L=215.9mm) 6: Tube (L=1524mm)</p>



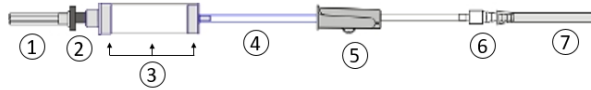
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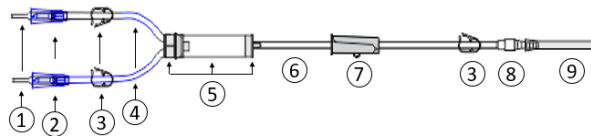
EMC4002A



Components:

- 1: Protective Cap
- 2: Spike
- 3: Non-vented chamber with mid-size chamber
- 5: Roller Clamp
- 6: Catheter Adaptor
- 7: Silicone Tube
- 4: Tube (L=1753mm)

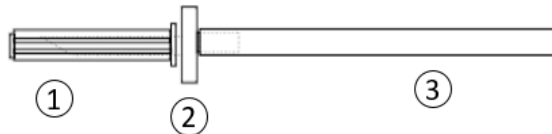
EMC4047



Components:

- 1: Urology Easy-flow protector
- 2: Urology Easy-flow spike
- 3: Large Medical Clamp
- 5: Manual asbl urology chamber
- 7: Roller clamp
- 8: Catheter Adaptor
- 9: Silicone Tube
- 4: Tube (L=229mm)
- 6: Tube (L=1524mm)

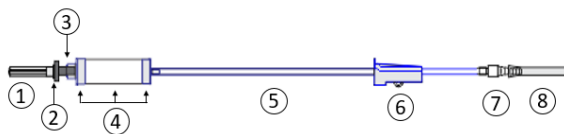
RMC4916



Components:

- 1: Protective Cap
- 2: Spike
- 3: Tube (L=152mm)

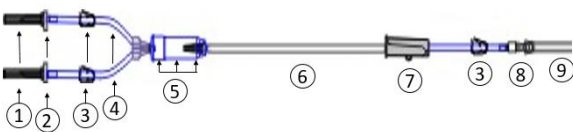
E5MC4002



Components:

- 1: Protective Cap
- 2: Spike
- 4: Non-DEHP Urology Single lead chamber
- 6: Roller Clamp
- 7: Catheter Adaptor
- 8: Silicone Tube
- 3: Non-DEHP tube (L=44mm)
- 5: Non-DEHP tube (L=1753mm)

EMC4015N



Components:

- 1: Protective Cap
- 2: Spike
- 3: Large Medical Clamp
- 5: Non-DEHP irrigation double lead chamber
- 7: Roller clamp
- 8: Catheter Adaptor
- 9: Silicone Tube
- 4: Non-DEHP Tube (L=415mm)
- 6: Non-DEHP Tube (L=1676mm)

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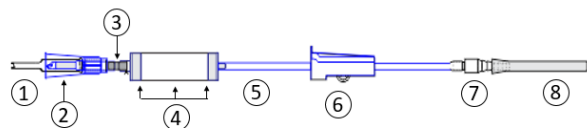
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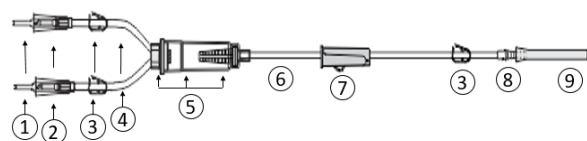
EMC4042



Components:

- 1: Urology Easy-flow protector
- 2: Urology Easy-flow spike
- 4: Non-DEHP Urology single lead chamber
- 6: Roller Clamp
- 7: Catheter Adaptor
- 8: Silicone Tube
- 3: Non-DEHP Tube (L=44mm)
- 5: Non-DEHP Tube (L=1753mm)

EMC4055N



Components:

- 1: Urology Easy-flow protector
- 2: Urology Easy-flow spike
- 3: Large Medical Clamp
- 5: Non-DEHP irrigation double lead chamber
- 7: Roller clamp
- 8: Catheter Adaptor
- 9: Silicone Tube
- 4: Non-DEHP Tube (L=415mm)
- 6: Non-DEHP Tube (L=1676mm)

VMC4005



Components:

- 1: Protective Cap
- 2: Spike
- 3: Large Medical Clamp
- 5: Non-DEHP Y connector
- 7: Catheter Adaptor
- 8: Silicone Tube
- 4: Non-DEHP Tube (L=229mm)
- 6: Non-DEHP Tube (L=1676mm)

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3. REFERENCE DOCUMENTS

REFERENCE NUMBER	TITLE
BXU535425	Irrigation Sets (Malta Access Codes) – User Needs and Intended Use
1277545	Viaflex Irrigation Hazard and Interoperability Assessment (HAZOP)
1248528	Clinical Evaluation Report: Non-Invasive Intravenous Therapy Devices
63129	Access Validation Study

4. DESIGN VALIDATION OVERVIEW

The products in scope of this validation report have been on the market for more than ten years, and any recent codes make use of the same components but in different configurations. All codes in scope of this document are CE marked. Majority of the Malta Access Portfolio product codes are also CE marked (the first CE mark for Malta Access Products was in 1995).



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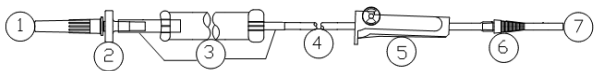
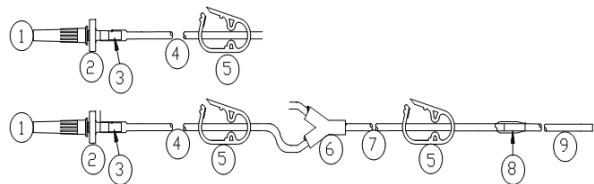
Clinical Evaluation Report:

A Clinical Evaluation Report (CER), document # 1248528, is available for the Irrigation Sets. The report evaluates the clinical risks and benefits associated with the products, and aims to demonstrate that the intended purpose of the Irrigation Sets and the claims made in relation to their clinical safety and performance are achieved.

Design Validation Study on similar products:

A successful validation was conducted on a number of different products, which are representative product codes of the products in scope, ensuring that the final products conform to the determined UNI. The validated codes in design validation study 63129 are listed in Table 2.

Table 2: Product codes validated as per study 63129

DHF Family: Irrigation Sets (validated per 63129)	
<p><u>2C4040</u></p> 	<p>Components:</p> <p>1: Protective Cap 2: Spike 3: Irrigation Chamber 5: Roller Clamp 6: Catheter Adaptor 7: Silicone tube 4: Tubing</p>
<p><u>2C4005</u></p> 	<p>Components:</p> <p>1: Protective Cap 2: Spike 3,8: Tube bushing 5: Notch Clamp 6: Y-Connector 9: Silicone Tube 4,7: Tubing</p>

The listed validated irrigation sets in Table 2 can be used as representatives to validate the Irrigation Set Codes in scope of this report in view of the following facts:

- 2C4040 and 2C4005 codes are irrigation sets within the Global Baxter portfolio which have the same intended use to administer irrigation solution from the solution container to the irrigation site and/or surgical sterile field. They include protective caps, spikes, irrigation chambers, notch clamps, roller clamps, catheter adaptors, silicone tubes and other different components as the products in scope of this report.

In addition, the listed representative codes are used similarly to the Irrigation Sets in scope given that:

- they are used in the same environment.
- they are used by the same users (Healthcare professionals).
- they have the same intended uses.

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- they are used in the same manner. Use steps for all codes are available in the Viaflex Irrigation Hazard and Interoperability Assessment (HAZOP), document # 1277545.

Hence attachment 1 shows how each representative code can be used to validate the UNIUs of the Irrigation Sets in scope of this study, with an explanation of the validation method used.

Therapy simulation testing was carried out on representative codes

As part of the Shelf Life Program for the Malta and Tunisia products, a test on the Therapeutic Performance is being conducted. A therapy simulation as per product's instruction for use (IFU) (where available) and feedback from PDO is performed to demonstrate functionality of the products. The therapy simulation covers the entire use of the product from taking the set out of its pouch, the actual usage of the product and up to the disconnection and disposal of the set.

Therapy simulation testing was performed on the irrigation codes in scope of this report (refer to study packages referenced in Table 3). The test was performed by trained operators, and on 28 units from each code which have gone through the normal manufacturing process, including sterilization and ageing as indicated in the respective studies. Testing was performed in a simulation laboratory (in house) that mimic actual use environment (i.e. health care institutions) working conditions. This approach was taken as the type of product misuse scenarios that occur in the actual use environment, can be mirrored practically through the testing done in the laboratory (in-house). Thus, simulation testing activities on the product performed in-house is deemed equivalent to that performed in the actual use environment.

Table 3: Therapy simulation tests on the irrigation codes in scope

Irrigation set	Therapy Simulation Study Reference
7400009A	79096
7401010A	77592
E5MC4007N	80084
EMC4002A	76757
EMC4047	79623
RMC4916	BXU530677
E5MC4002	75413
	75414
EMC4015N	75414
EMC4042	75413
EMC4055N	75414
VMC4005	75414

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5. CONCLUSION

Through the points mentioned in the Design Validation Overview section above it can be concluded that all the user needs and intended uses listed in Attachment 1 are fully validated.

6. ATTACHMENTS

Attachment 1: User Needs and Intended Uses Validation Matrix

7. ARCHIVAL

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Reports	TcU

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TcU ELECTRONIC SIGNATURE REPORT

REVISION INFORMATION

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Zammit, Malcolm	SME	Document Review - SME & Quality	25-Sep-2019	Approved
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