Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

Anna Nowicka
Digitally signed by Anna Nowicka
Date: 2023.01.11 12:25:14 +01'00'

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 062680 0155 Rev. 00

Manufacturer:

Baxter Healthcare SA
8010 Zürich
SWITZERLAND

Facility(ies):

Baxter Healthcare S.A.
Thurgauerstrasse 130, 8152 Glattpark (Opfikon),
SWITZERLAND

Product Category(ies): **Single use devices and pressure regulator including accessory for the application of surgical sealants**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: **713163333**

Valid from: 2020-02-21
Valid until: 2024-05-26

Date, 2020-02-21

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Declaration of Conformity

According to:	**Council Directive 93/42/EEC (MDD)**
Annexes: II, excluding 4	
Notified Body Certificate(s): G1 062680 0155 Rev.00	
Notified Body's name and address: Notified Body's identification number:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany 0123
Manufacturer's name:	Baxter Healthcare SA
Manufacturer's address:	8010 Zürich Switzerland
EC Representative's address: not applicable	
+++We declare under our sole responsibility that the following product(s) conform to the applicable provisions of the above-mentioned Directive:+++	
Product Family/Category:	Single use devices and pressure regulator including accessory for the application of surgical sealants
Code Numbers:	See "CE Marked Product Code List"

+++This declaration is made on the following basis:

- The validity of this document shall not start earlier than the validity date of the corresponding EC Certificate.
- The DOC declares conformity to all product lots released within the above validity period.
- For Class I non-sterile / non-measuring: self-declaration of conformity.
- Compliance to standards and regulations as defined in the Technical Documentation and Essential Requirements Checklist.+++

Signature: _____ Zurich 07 Apr 2020

(Simone Diorio, VP Quality EMEA) *(Place, Date)*

CE-marked Product Code List
to the Declaration of Conformity

Business: Advanced Surgery

Certificate Number:	G1 062680 0155
Conformity Assessment Procedure:	Annex II, excluding (4)
Classification:	IIa
Sterilisation Method:	Gamma, ETO, n.a.
Facility:	Lessines (Belgium)
Product Category:	Single use devices and pressure regulator including accessory for the application of surgical sealants

Code	Description	Date of CE marking
1502323	DUPLOCATH 25	see BaxTRACs
1502324	DUPLOCATH 35 MIS	see BaxTRACs
1502325	DUPLOCATH 180	see BaxTRACs
3400662	DUPLOJECT System 2ml/4ml	see BaxTRACs
3400663	DUPLOJECT System 10ml	see BaxTRACs
3400666	DUPLOJECT Combi	see BaxTRACs
3400667	DUPLOJECT Combi P	see BaxTRACs
3400658	DUO Set A 2ml/4ml	see BaxTRACs
3400659	DUO Set A 10ml	see BaxTRACs
3400654	DUO Set 2ml/4ml	see BaxTRACs
3400655	DUO Set 10ml	see BaxTRACs
1504720	EASYSPRAY 2 bar, CE	see BaxTRACs
1502696	EASYSPRAY Air 800	see BaxTRACs
1504272	TISSEEL/ARTISS Spray Set (10 pack)	see BaxTRACs
1504273	TISSEEL/ARTISS Spray Set (single pack)	see BaxTRACs
1504271	TISSEEL/TISSUCOL Spray Set	see BaxTRACs
0600021	COSEAL Spray Set	see BaxTRACs

This report has been reviewed and verified by: _____ Date: 24. April 2020
(Dr. Susan Sümer)

Title: Mgr, Regulatory Affairs Global
Germany Adv Surg Regulatory