By Royal Charter

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 711371**

Issued To: **Avanos Medical, Inc**
5405 Windward Parkway
Alpharetta
Georgia
30004
USA

In respect of:

Introducer Kits for the Initial Placement of Feeding Tubes
Gastrointestinal Anchor Set

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-07-22** Date: **2020-03-08** Expiry Date: **2024-05-26**

...making excellence a habit.™

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 711371

Issued To:

Avanos Medical, Inc
5405 Windward Parkway
Alpharetta
Georgia
30004
USA

Product Code	Device Name & Type	Intended purpose per IFU	Classification
98430	Introducer Kit, MIC-KEY G, 12 FR	To facilitate the primary placement of the gastric, jejunal, or gastric-jejunal enteral feeding tubes.	III
98431	Introducer Kit, MIC-KEY G, 14 FR		
98432	Introducer Kit, MIC-KEY G, 16 FR		
98433	Introducer Kit, MIC-KEY G, 18 FR		
98434	Introducer Kit, MIC-KEY G, 20 FR		
98437	Introducer Kit, MIC-KEY J & TJ, 16 FR		
98438	Introducer Kit, MIC-KEY J & TJ, 18 FR		
98701	Gastrointestinal Anchor Set	To affix the stomach to the anterior abdominal wall facilitating primary placement of enteral feeding tubes.	

First Issued: **2019-07-22** Date: **2020-03-08** Expiry Date: **2024-05-26**

...making excellence a habit.™

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 711371

Issued To:

Avanos Medical, Inc
5405 Windward Parkway
Alpharetta
Georgia
30004
USA

Product Code	Device Name & Type	Intended purpose per IFU	Classification
10250	MIC-KEY* G-12 Laparoscopic Introducer Kit	To facilitate the primary placement of the gastric, jejunal, or gastric-jejunal enteral feeding tubes.	III
10230	MIC-KEY* G-14 Laparoscopic Introducer Kit		
10240	MIC-KEY* G-16 Laparoscopic Introducer Kit		
10237	MIC-KEY* G-18 Laparoscopic Introducer Kit		
10226	MIC-KEY* G-20 Laparoscopic Introducer Kit		
10249	MIC-KEY* J/TJ-16 Laparoscopic Introducer Kit		
10229	MIC-KEY* J/TJ-18 Laparoscopic Introducer Kit		

First Issued: **2019-07-22** Date: **2020-03-08** Expiry Date: **2024-05-26**

...making excellence a habit.™

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 711371

Issued To:

Avanos Medical, Inc
5405 Windward Parkway
Alpharetta
Georgia
30004
USA

Certificate History

Date	Reference Number	Action
22 July 2019	9772185	First issue. Mirror certificate of CE 621871
22 July 2019	9772185 - correction	Certificate correction: name of legal manufacturer & zip code
Current	3041880	Renewal

First Issued: **2019-07-22** Date: **2020-03-08** Expiry Date: **2024-05-26**

...making excellence a habit.™

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.