



Notified Body 1023  
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

## EC Certificate - Production Quality Assurance No. 11 0454 QS/NB

The quality system of manufacturer

**BJD Medical Production s.r.o.**

**Knínická 1577, 664 34 Kuřim, Czech Republic**

has been certified as meeting the requirements of

**Directive 93/42/EEC**  
**on medical devices, Annex V**

for the following product category(ies):

**Suction Connecting Tube**

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. The Notified Body has audited this system with limitation to those aspects of manufacture concerned with securing and maintaining sterile conditions. This part of quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance.

**Valid from:** 2020-05-19  
**Valid until:** 2024-05-27  
**First Issued:** 2011-05-26  
**Revision:** b



Date: 2020-05-19

**Mgr. Jiří Heš**  
Representative of the Notified Body No. 1023



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## Annex to EC Certificate No. 11 0454 QS/NB issued for manufacturer:

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### Product(s):

**Name:** Suction Connecting Tube  
**Trade name(s):** -  
**Class:** Is  
**GMDN:** 16779  
**Model(s):**

#### a) Chariére: CH 25

REF	Product description
01.25.201	Suction Connecting Tube, tube - tube, 2 m
01.25.251	Suction Connecting Tube, tube - tube, 2,5 m
01.25.100	Suction Connecting Tube, tube - tube, 1 m
01.25.125	Suction Connecting Tube, funnel - tube, 1,25 m
01.25.180	Suction Connecting Tube, shortened funnel - loose vacuum control, 1,8 m
01.25.186	Suction Connecting Tube, funnel - vacuum control, 1,8 m
01.25.200	Suction Connecting Tube, funnel - funnel, 2 m
01.25.208	Suction Connecting Tube, shortened funnel - vac. control, 2 m
01.25.209	Suction Connecting Tube, shortened funnels on both sides- loose vacuum control, 2 m
01.25.210	Suction Connecting Tube, funnel - vacuum control, 2 m
01.25.211	Suction Connecting Tube, funnel - loose vacuum control, 2 m
01.25.212	Suction Connecting Tube, shortened funnels on both sides- loose vacuum control, 2 m
01.25.220	Suction Connecting Tube, funnel - tube, 2 m
01.25.250	Suction Connecting Tube, funnel - funnel, 2,5 m
01.25.260	Suction Connecting Tube, funnel - vacuum control, 2,5 m

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REF	Product description
01.25.300	Suction Connecting Tube, funnel - funnel, 3 m
01.25.310	Suction Connecting Tube, funnel - vacuum control, 3 m
01.25.320	Suction Connecting Tube, funnel - tube, 3 m
01.25.350	Suction Connecting Tube, funnel - funnel, 3,5 m
01.25.359	Suction Connecting Tube, funnel - tube piece, 2 m
01.25.360	Suction Connecting Tube, funnel - tube piece, 2,5 m
01.25.375	Suction Connecting Tube, funnel - tube piece, 3,5 m
01.25.420	Suction Connecting Tube, funnel - tube, 4 m
01.25.425	Suction Connecting Tube, tube - tube, 4 m
01.25.500	Suction Connecting Tube, funnel - funnel, 5 m
01.25.525	Suction Connecting Tube, tube - tube, 5 m
01.25.575	Suction Connecting Tube, funnel - tube piece, 5 m

### b) Charière: CH 30

REF	Product description
01.30.152	Suction Connecting Tube, funnel - tube, 1,5 m
01.30.159	Suction Connecting Tube, vacuum control - tube, 1,5 m
01.30.200	Suction Connecting Tube, funnel - funnel, 2 m
01.30.210	Suction Connecting Tube, funnel - vacuum control, 2 m
01.30.217	Suction Connecting Tube, vacuum control - tube, 2 m
01.30.225	Suction Connecting Tube, tube - tube, 2 m
01.30.250	Suction Connecting Tube, funnel - funnel, 2,5 m
01.30.270	Suction Connecting Tube, funnel - tube, 2,5 m
01.30.300	Suction Connecting Tube, funnel - funnel, 3 m
01.30.302	Suction Connecting Tube, shortened funnels on both sides - loose vacuum control, 3 m
01.30.310	Suction Connecting Tube, funnel - vacuum control, 3 m

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<b>REF</b>	<b>Product description</b>
01.30.320	Suction Connecting Tube, funnel - tube, 3 m
01.30.325	Suction Connecting Tube, tube - tube, 3 m
01.30.350	Suction Connecting Tube, funnel - funnel, 3,5 m
01.30.355	Suction Connecting Tube, funnel - tube, 3,5 m
01.30.400	Suction Connecting Tube, funnel - funnel, 4 m
01.30.419	Suction Connecting Tube, vacuum control - tube, 4 m
01.30.420	Suction Connecting Tube, funnel - tube, 4 m
01.30.500	Suction Connecting Tube, funnel - funnel, 5 m
01.30.520	Suction Connecting Tube, funnel - tube, 5 m
01.30.600	Suction Connecting Tube, funnel - funnel, 6 m

### **Facility(ies):**

BJD Medical Production s.r.o.  
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### Certificate History:

Revision	Date	Reference Number	Action
	2011-05-26	803601135	Certification
a	2016-05-16	803602506	Re-certification process
b	2020-05-19	833600192	Re-certification process



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