

PRO-MED INSTRUMENTE GMBH

Gänsäcker 9

78532 Tuttlingen

Tuttlingen, 12.06.2017

**CLASSIFICATION TABLE OF MEDICAL EQUIPMENT**

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Gänsäcker 9, 78532 Tuttlingen

as the owner of the medical equipment, we hereby state the Risk Classification of our medical equipment according to Directive 93/42/EEC; Annex IX. This Risk Classification applies to the products listed in Annex I.

Description	applicable
Transient (less than 60 Min)?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Short-term (up to 30 days)?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Long-term (more than 30 days)?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Invasive device?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Natural body orifice?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Surgically invasive device?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Implantable device?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Reusable surgical instrument?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Active device?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Active therapeutic device?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Active diagnostic device?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Central circulatory system?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Central nervous system?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
System or procedure kit?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Software controlled?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

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Description	applicable
Several rules applicable? (If yes, rule with highest risk class applies)?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Rule	Applicable Definition	Class
<b>93/42/EEC-Annex IX, Rule 5</b>	All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device: - are in Class I if they are intended for transient use	I

**Acknowledged classification in Vietnam**

The regulation on recognition of medical device classification results from the 15<sup>th</sup> of November 2016 issues the stipulating conversion between classifications in various countries to the classification in Vietnam. In this case the Conversion guideline for the acknowledged results of medical equipment which is not in vitro diagnostics medical equipment is applicable. This guideline is depicted in the following table.

Classification of medical equipment in other countries							Conversion result of the classification in Vietnam
The countries of ASEAN	The countries of European region	Australia	Canada	Korea	Japan	USA	
A	I	I	I	1	I	I	A
B	IIa	IIa	II	2	II		B
C	IIb	IIb	III	3	III		C
D	III	III	IV	4	IV	III	D

According to this guideline class I medical equipment in the countries of European region is converted to class A in Vietnam.

Legal representative of establishment

Ralph Dinkelmann, Managing Director

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 Gänsäcker 9  
 78532 TUTTLINGEN

## Unterschriftsbeglaubigung

Die vorstehend, vor mir als eigenhändig vollzogen anerkannte Unterschrift von

Herrn Ralph Dinkelman, geschäftsansässig Gänsäcker 9, 78532

Tuttlingen, geb. am 12. Januar 1965,

- persönlich bekannt -

beglaubige ich hiermit öffentlich.

Tuttlingen, den 23. Juni 2017

Urkundenrolle Nr. 1797/2017



Notar

  
Werner

Nr. 910 E - 427/17

Die Echtheit vorstehender Unterschrift

des Notars Werner  
mit dem Dienstsitz  
in Tuttlingen

und die Echtheit des begedrückten Dienststempels/  
Dienstsiegels werden hiermit bestätigt. Zugleich wird  
bescheinigt, dass der Vorgenannte zur Vornahme der  
Amtshandlung gesetzlich befugt war.

Rottweil, den 29. Juni 2017  
Präsident des Landgerichts:  
In Vertretung:




  
Dr. Thilo Rebmann  
Vizepräsident des Landgerichts

Kosten:

Geb. gem. Geb. Verz.  
Nr. 1310 zu § 4 Abs. 1  
JVKostG: 20,00 €



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tại Frankfurt am Main, CHLB Đức

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Country: **Giấy tờ, tài liệu này**  
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