



Product Service

## Appendix A ?

Details on product groups and categories (conformity assessment procedure in accordance with Directive 93/42/EEC (MDD))



Manufacturer:



Application identification:

### Device details per certificate number ?

This form may be used as a list if filled accurately. You can also use it as a template and provide **the same information** in other formats (e.g. Excel).

Certificate number:



Category\*

All article/model numbers

Article/Model names



Class



Sterile



Rule

UMDNS code



OEM device

OEM name

Please enclose the relevant certificates of the OEM (Original Equipment Manufacturer).



Annex IX, Rule 17



Annex IX, Rule 13

Category*	All article/model numbers	Article/Model names	Class	Sterile	Rule	UMDNS code	OEM device	OEM name Please enclose the relevant certificates of the OEM (Original Equipment Manufacturer).	Annex IX, Rule 17	Annex IX, Rule 13
				<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>

\* Please quote here:

- Consistent with proposed certification scope.
- For all classes of Medical Devices: the respective scope expression on the basis of [NBOG BPG 2009-3](#) including the special MDS codes e.g nano materials.
- Additionally for class IIb/III Medical Devices: the respective preferred terms from the [GMDN](#).
- Only in cases where the scope expression or preferred terms are not existing: indicate your own category.