

Appendix 1 NiSV device form

Please fill in this form individually for each type of device. If the device in question is intended to be kept in stock as a "NiSV-free" device, the obligation to provide proof of compliance with the limit values applies. For NiSV-free devices, please fill in the device form "NiSV-free device".

The technical data can be found in the operating instructions, missing data should be filled in by the sellers/manufacturers. If not all the data can be obtained, it is only necessary to exceed the limit values to make the device reportable.

Ultrasonic unit [NiSV §2 (1) a, b].		
Unit name:	Value	Application
Frequency in [Hz]:		
Power at the applicator in [W/cm ²].		
Mechanical index		
Thermal index		

Laser device [NiSV §2 (2)].		
Unit name:	Value	Application
Laser class according to DIN EN 60825-1:		
Wavelength in [nm]:		

Intense incoherent pulsed light (IPL/SHR) - device [NiSV §2 (3)].		
Unit name:	Value	Application
Risk class according to DIN EN 62471:		
Energy density in [J/cm ²]:		

High frequency device [NiSV §2 (4) a, b, c].		
Unit name:	Value	Application
Frequency(s) in [Hz].		
Specific absorption rate (SAR) in [W/kg]		
Internal electric field strength in [V/m].		
Contact currents in [mA].		

Low frequency device [NiSV §2 (5)].		
Unit name:	Value	Application
Frequency(s) in [Hz].		
Internal electric field strength in [V/m].		
Contact currents in [mA].		

Direct current unit [NiSV §2 (6)].		
Unit name:	Value	Application
Contact current in [mA].		
Current density in [mA/m ²].		

Magnetic field device [NiSV §2 (7)].		
Unit name:	Value	Application
Magnetic field in [mT].		

Limit values NiSV

Paragraph	indent	Technology	Limit value
§2	1.a)	Ultrasound	> 50 mW/cm ² at the eye >100 mW/cm ² on the body
	1.b)		Mechanical index > 0,4 Thermal index > 0,7
	2.	Laser classes	1c, 2M, 3R, 3B, 4
	3.	intensive light sources with incoherent optical radiation	With effect on the target tissue
	4.a	High-frequency equipment	>100 KHz <10 GHz
	Annex 1.a)	Specific absorption rates or power densities	SAR >2 W/kg at head
			SAR > 4 W/kg on the body
	4.b)		>100 KHz <10 MHz
	Annex 1.b)	Internal electric field strength in V m ⁻¹ (effective)	1.35x 10 ⁻⁴ x f (f in Hz)
	4.c)		>100 KHz <110 MHz
	Annex 1.c)	Contact flows	>20 mA
	5.	Low-frequency equipment	>1 <100 KHz
	Annex 1, 2.a)		Internal field strengths depending on frequency
	Annex 1, 2.b)		Contact currents Frequency dependent

Note: If the specified limit values are violated by only one device parameter, the device falls under the regulation of the NiSV.