

NiSV-notification-free device

I hereby declare for the following device that no limit values according to §2 NiSV are exceeded.

Device name:	
Manufacturer:	
Manufacture date:	
Model:	
Serial number:	

Note: It is sufficient if only one limit value is exceeded to make the device reportable. Missing measured values are interpreted as a boundary limit violation. Please enter the test standard along with the required measured values.

Ultrasound		
Parameters	Method	measured value
Frequency - measurement in [Hz]:		
Power at the applicator in [W/cm ²].		
Mechanical index		
Thermal index		
Laser		
Laser class:	EN 60825-1	
Wavelength in [nm]:		
IPL/SHR		
Risk class:	EN 62471	
Energy density in [J/cm ²]:		
Radio Frequency		
Frequency(s) in [Hz].		
Specific absorption rate in [W/kg]		
Internal electric field strength in [V/m].		
Contact currents in [mA].		
Low frequency		
Frequency(s) in [Hz].		
Internal electric field strength in [V/m].		
Contact currents in [mA].		
Direct current		
Contact current in [mA].		
Current density in [mA/m ²].		
Magnetic field		
Magnetic field in [mT].		

Filled in by:

Date:

Signature:

E-mail (for queries only):

Limit values

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

Limit values which must not be exceeded if the device is declared exempt from the obligation to report to the NiSV regulation. source: NiSV, Annex 1

1. high-frequency equipment (Article 2(1)(4))

a)

Basic restrictions on electromagnetic fields or currents:

Frequency range f	Specific absorption rate SAR at head and torso (W/kg)	Specific absorption rate SAR at the extremities (W/kg)	Power density S (W/m ²)
100 kHz - 10 GHz	2	4	
10 GHz - 300 GHz			10
Notes	Averaged over 6-minute intervals and 10 g coherent body tissue		Averaged over 68/f ^{1.05} -minute intervals and 20 cm ² exposed area (f in GHz) For local maximum values averaged over 1 cm ² , 200 W/m ² apply

Paragraph	indent	Technology	Limit value
§2			
	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)

b)

Basic limits for the internal electric field strength:

Frequency range	Internal electric field strength in V m ⁻¹ (effective)
100 kHz - 10 MHz	1.35x 10 ⁻⁴ x f (f in Hz)

Paragraph	indent	Technology	Limit value
§2			
	Annex 1.c)	Contact flows	>20 mA

c)
Reference values for contact currents:

Frequency range	Maximum contact current in mA
100 kHz - 110 MHz	20

The contact current must be summed over all electrodes.

Paragraph	indent	Technology	Limit value
§2			
	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

2. low-frequency equipment (Article 2(1)(5))

a)
Basic restrictions for electric or magnetic fields or currents:

Exposure	Frequency range	Internal electric field strength in V m ⁻¹ (effective)
CNS fabric on the head	1 Hz - 10 Hz	0.1/f (f in Hz)
	10 Hz - 25 Hz	0,01
	25 Hz - 1,000 Hz	4x 10 ⁻⁴ x f (f in Hz)
	1,000 Hz - 3 kHz	0,4
Tissue on the head and body	3 kHz - 100 kHz	1.35x 10 ⁻⁴ x f (f in Hz)
	1 Hz - 3 kHz	0,4
	3 kHz - 100 kHz	1.35x 10 ⁻⁴ x f (f in Hz)

b)
Reference values for contact currents:

Frequency range	Maximum contact current in mA
1 Hz - 2.5 kHz	0,5
2.5 kHz - 100 kHz	0.2x f (f in kHz)

The contact current must be summed over all electrodes.

3. limit value exhaustion of equipment using several frequencies simultaneously (§ 2(1), points 4 and 5)

a)

Summation formulae for specific absorption rates SAR and power densities S

$$\sum_{i=100 \text{ kHz}}^{10 \text{ GHz}} \frac{\text{SAR}_i}{\text{SAR}_B} + \sum_{i>10 \text{ GHz}}^{300 \text{ GHz}} \frac{S_i}{S_B} \geq 1$$

where SAR_i = contribution to SAR from exposure to the frequency i, SAR_B = SAR basic restriction as defined in Annex 1(1a), S_i = contribution to power density from exposure to the frequency i, S_B = basic power flux density restriction as defined in Annex 1(1a)

b)

Summation formulae for induced electric fields E_i

$$\sum_{j=1 \text{ Hz}}^{10 \text{ MHz}} \frac{E_{i,j}}{E_{B,j}} \geq 1$$

where E_{i,j} = contribution of the induced electric field at frequency j, E_{B,j} = basic restriction of the induced electric field at frequency j, according to Annex 1, points 1 a) and 2 a)

c)

Summation formulae for contact currents I_j

$$\sum_{j=1 \text{ Hz}}^{10 \text{ MHz}} \frac{I_j}{I_{R1,j}} \geq 1$$

$$\sum_{j=100 \text{ kHz}}^{110 \text{ MHz}} \left(\frac{I_j}{I_{R2,j}} \right)^2 \geq 1$$

with

I_j = contribution of the contact current at frequency j, I_{IR1,j} = reference value of the contact current at frequency j, according to Annex 1 point 1 c) I_{IR2,j} = reference value of the contact current at frequency j, according to Annex 1 point 2 b)