

**Accreditation scope**

Name of the accredited subject: **Procedo International Certification s.r.o.,**  
Nevädzová 3355/18B  
900 31 Stupava

<b>№</b>	<b>Main Technical Areas</b>	<b>Technical Areas</b>
<b>1</b>	<b>Non-active Medical Devices</b>	General non-active, non-implantable medical devices
<b>2</b>		Non-active implants
<b>3</b>		Devices for wound care
<b>4</b>		Non-active dental devices and accessories
<b>5</b>		Non-active medical devices other than specified above
<b>6</b>	<b>Active Medical Devices (Non-Implantable)</b>	General active medical devices
<b>7</b>		Devices for imaging
<b>8</b>		Monitoring devices
<b>9</b>		Devices for radiation therapy and thermo therapy
<b>10</b>		Active (non-implantable) medical devices other than specified above
<b>11</b>	<b>In Vitro Diagnostic Medical Devices (IVD)</b>	Reagents and reagent products, calibrators and control materials for: Clinical Chemistry Immunochemistry (Immunology) Haematology/Haemostasis/ Immunohematology Microbiology Infectious Immunology Histology/Cytology Genetic Testing
<b>12</b>		In Vitro Diagnostic Instruments and software
<b>13</b>		IVD medical devices other than specified above
<b>14</b>	<b>Sterilization Method for Medical Devices</b>	Ethylene oxide gas sterilization (EOG)
<b>15</b>		Moist heat
<b>16</b>		Aseptic processing
<b>17</b>		Radiation sterilization (e.g. gamma, x-ray, electron beam)
<b>18</b>		Sterilization method other than specified above
<b>19</b>	<b>Devices incorporating / utilizing specific substances / technologies</b>	Medical devices incorporating medicinal substances
<b>20</b>		Medical devices utilizing tissues of animal origin
<b>21</b>		Medical devices utilizing nanomaterials
<b>22</b>		Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed
<b>23*</b>	<b>Parts or services</b>	Raw materials
<b>24*</b>		Components
<b>25*</b>		Subassemblies
<b>26*</b>		Calibration services
<b>27*</b>		Distribution services
<b>28*</b>		Maintenance services
<b>29*</b>		Transportation services
<b>30*</b>		Other services

\* Note: In the designated areas, the certification body can not issue accredited certificate.

Workplaces of Certification Body, where certification activities are exercised (workplaces, where key activities are exercised, are marked with star):

<b>№</b>	<b>Name and address of workplace</b>
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