

# ISO 7199:2009-04 (E)

## Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)

<b>Contents</b>		<b>Page</b>
Foreword .....		iv
Introduction .....		v
<b>1</b>	<b>Scope .....</b>	<b>1</b>
<b>2</b>	<b>Normative references .....</b>	<b>1</b>
<b>3</b>	<b>Terms and definitions .....</b>	<b>2</b>
<b>4</b>	<b>Requirements .....</b>	<b>3</b>
<b>4.1</b>	<b>Biological characteristics .....</b>	<b>3</b>
<b>4.2</b>	<b>Physical characteristics .....</b>	<b>3</b>
<b>4.3</b>	<b>Performance characteristics .....</b>	<b>3</b>
<b>5</b>	<b>Tests and measurements to determine compliance with this International Standard .....</b>	<b>4</b>
<b>5.1</b>	<b>General .....</b>	<b>4</b>
<b>5.2</b>	<b>Biological characteristics .....</b>	<b>4</b>
<b>5.3</b>	<b>Physical characteristics .....</b>	<b>5</b>
<b>5.4</b>	<b>Performance characteristics .....</b>	<b>5</b>
<b>6</b>	<b>Information supplied by the manufacturer .....</b>	<b>8</b>
<b>6.1</b>	<b>Information to be given on the oxygenator .....</b>	<b>8</b>
<b>6.2</b>	<b>Information to be given on the packaging .....</b>	<b>8</b>
<b>6.3</b>	<b>Information to be given in the accompanying documents .....</b>	<b>9</b>
<b>6.4</b>	<b>Information to be given in the accompanying documents in a prominent form .....</b>	<b>10</b>
<b>7</b>	<b>Packaging .....</b>	<b>10</b>
Bibliography .....		11