

## EU – DECLARATION OF CONFORMITY

We **S. JEE Enterprises.**, declare on our own responsibility that the Medical Device(s).

GMDNS Code	UMDNS Code	Description
13755	13750	Stethoscope, aluminium
<p><b>S. JEE.</b> Stethoscope is used for listening to the heartbeat of a fetus. The Pinard Horn is a hollow horn-shaped stethoscope approximately 6 inches in length, that is pressed against the patients stomach. It is considered to be a more accurate device than the Doppler Fetal Monitor.</p>		
<p><b>Product Model(s):</b> 43 960 10</p>		
<p><b>Basic UDI-DI:</b> <b>896404396010LG</b></p>		

GMDNS Code	UMDNS Code	Description
11950	11949	Hammer, babinsky
<p><b>S. JEE.</b> A hand-held manual instrument designed to be used by an examining physician to gently tap near a patient's joints to test reflexes (e.g., patellar, ankle reflexes). It consists of a handle and shaft typically made of stainless steel, and has a head that may be ring, wedge, or dome shaped and is made of a soft material (e.g., rubber or plastic). Some devices may be fitted with a spike, brush, or other detachable component at the proximal end that can be used for neurological examinations. This is a reusable device.</p>		
<p><b>Product Model(s):</b> 41 581 00</p>		
<p><b>Basic UDI-DI:</b> <b>896404158100JS</b></p>		

The product(s) specified are **Class 1 Medical Devices** and meets according to **Annex VIII** of Medical Device Regulations. The product fulfills all the technical requirements listed in the **Annex II** of the **Medical Devices Regulations MDR 2017/745**. Conformity assessment was carried out on the basis of the **Annex IX** of the **Council MDR 2017/745**.

The Technical File is maintained at:

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Whereas our all products are manufactured under the guidelines of following international standards:

Standard	Description
ISO-13485:2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
ISO-9001:2015	Quality Management System - Requirements
EU 2017/745	Regulations and Council of European Union on Medical Devices
ASTM F899-12b	Standard Specification for Wrought Metals for Surgical Instruments
ASTM A276 - 17	Standard Specification for Stainless Steel Bars and Shapes
ISO 14971:2019	Medical devices Application of risk management to medical devices
BS.EN-1041:2008	Information Supplied by the Manufacturer with Medical Devices
EN 62366:2008	Medical devices — Application of usability engineering to medical devices
ISO-7153-1:2016	Surgical Instruments – Materials – Part 1: Metals
ISO-17664:2004	Sterilization of Medical Devices – Information to be provided by the manufacturer for the processing of re-sterilization medical devices
BS EN ISO 15223-1:2012	Symbols to be used in the labeling of medical devices
cGMP	Current Good Manufacturing Practices

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Sign & Stamp