HBC NAVTEX LLC
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DECLARATION

HBC NAVTEX LLC declares that the medical devices manufactured comply with the defined in point 13 of annex I to Directive 93/42/EC and as defined in point 13 of annex I of Decree-Law No 145/2009, of 17th June.

The devices manufactured by HBC NAVTEX LLC, are class I devices and these are conventional products and in common use:
The devices that manufactured by HBC NAVTEX LLC is the family of medical bleached gauze cotton non sterile in rolls (2 types- without X-Ray threads and with X-Ray threads):

- 13 threads/cm² - code 6498/22-140, 6498/22-160, 6498/22-190, 6498/22-320, 6498/22-330, 6498/22-310;
- 17 threads/cm² - code 6498/21-310, 6498/21-410, 6498/21-520, 6498/21-530, 6498/21-540, 6498/21-550, 6498/8-240, 6498/8-290, 6498/8-310, 6498/8-330, 6498/8-340, 6498/8-360, 6498/8-370, 6498/8-380, 6498-760;
- 20 threads/cm² - code 6498-670, 6498-690, 6498-750, 6498-770, 6498-780, 6498-790,

In the individual package, in which the devices are packed, the labeling refers to the method of use of the device, the warnings and the maintenance of sterility.

In the form of symbols, in accordance with the harmonized standards, are also mentioned, lot, date expiration and manufacture, conditions of sterilization, recycling, etc.

In this way it is ensured the correct and safe use of devices, with the particulars given on the label, without the instruction sheet.

"SANFARM-PRIM" S.A. Nr. 1002600039072

NAVOLOKI, REGION IVANOVO, RUSSIAN FEDERATION
01 AUGUST 2017

Quality Vice-Diretor N.I. Zamyslova
HBC NAVTEX LLC

Digitally signed by Harea Stefan
Date: 2021.09.13 09:15:36 EEST
Reason: MoldSign Signature
Location: Moldova

ISO 13485:2003
ISO 9001:2008