HBC NAVTEX LLC
Russian Federation, 155830, Ivanovo region, Navoloki, Promyshlennaya str., 1
Tel: +7 493 2591111 Tel/Fax: +7 493 3197614 e-mail: medical@atdl.ru
https://www.tdl-textile.ru/en/

Declaration of Comformity CE

(Medical Device Class I)

Authorised Representative of the Manufacturer HBC NAVTEX LLC that established in Portugal :

CET MSU Portugal Unipessoal Lda

Address or Registered place of business:

Avenida dos Bons Amigos № 5 1°B 2735-076 Agualva Portugal

Declares:

The devices that manufacture HBC NAVTEX LLC is the family of medical gauze bleached 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, 6498/22-310, 6498/22-320, 6498/22-330;
- 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,

complies with the essential requirements set out in Annex I to Directive 93/42 / EEC of 14 June, as amended and Decree-Law No 145/2009 of 17 June compromise the clinical condition or the safety of patients, or the safety and health of users or, where appropriate, third parties, when used under the conditions and for the intended purpose, considering that any risks associated with the use are acceptable risks when compared to the benefit provided to patients and are compatible with a high degree of protection of health and safety.

Undertakes to:

♦ Create and update a process of systematic analysis of the experience gained from devices in the post-production phase, including the provisions referred to in annex XVI, of Decree No. 145/2009, of 17th June.

♦ Develop appropriate means to apply any necessary corrective actions, taking account of the nature and risks related to the product and to notify the Competent Authority about their incidents, such as:

- Any malfunction, deterioration or deterioration of the characteristics or behavior, as well as any imprecision, omission or insufficiency in the labeling or instructions for use of a device which are likely to cause or have caused the death or serious deterioration of the state of health of a patient, user or third party;

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Location: Moldova

- Any indirect damage resulting from an incorrect medical decision relating to a medical device when used in accordance with the instructions for use provided by the manufacturer;

- Any technical or medical reasons relating to the characteristics or performance of a device which, for the reasons referred to in the preceding subparagraphs, has led to a corrective safety action on the Portuguese market of the devices of the same type by the manufacturer.

- Other information that the experience demonstrates should be reported.

♦ Draw up the technical documentation and keep it up to date, including this statement, available to the Competent Authority for inspection purposes for five years from the last date of manufacture of the medical device.

Date: 06 / 09 / 2017

CET MSU PORTUGAL UNIPESSOAL LDA. NIF 514 149 043

CET MSU

Alexander Vladislavovich Dolgov

Director CET MSU PORTUGAL UNIPESSOAL LDA

N.I. Zamyslova

Quality Vice-Diretor
HBC NAVTEX LLC

ООО "ХБК "НАВТЕКС"