

**Декларація відповідності
медичних виробів № 002/2019**
*Declaration of conformity
of medical products № 002/2019*

Загальна назва виробів: <i>Common name of medical devices:</i>	Стенти для периферичних судин, стенти для ниркових судин, катетери для периферичної ангіопластики, мікросфери. <i>Stents for peripheral vessels, stents for renal vessels, catheters for peripheral angioplasty, microspheres</i>
Перелік виробів: <i>List of products:</i>	Дивіться у Додатку №1 <i>See Annex 1</i>
Виробник: <i>Manufacturer:</i>	Балтон Сп. з о.о., вул. Нови Свят, 7/14, 00-496, Варшава, Польща <i>Balton Sp. z o.o., address: Warsaw (P.C. 00-496) 7/14 Nowy Swiat Street</i>
Уповноважений представник: <i>Authorized representative:</i>	ТОВ «МЕД-ІМПОРТ», м. Київ, вул. Предславинська, буд. 57, кв. 78, індекс 03150, код ЄДРПОУ 42844275, тел.: +380 97 100 00 62 <i>Med-Import LLC, address: Kyiv, Ukraine 03150, Predslavynska street, 57, app. 78, identification code of enterprise: 42844275, Tel. +380 97 100 00 62</i>
Класифікація : <i>Classification:</i>	Згідно Додатка 2 Технічного Регламенту щодо медичних виробів, затвердженого постановою КМУ від 02.10.2013 № 753, клас потенційного ризику застосування ІІб <i>According to Annex 2 of the Technical regulations on medical products, approved by the CMU dated 02.10.2013 № 753, class of potential use risk IIb</i>
Процедура оцінки відповідності: <i>Conformity Assessment Route:</i>	Додаток 3 Технічного регламенту щодо медичних виробів, затвердженого постановою КМУ від 02.10.2013 № 753 <i>Annex 3 of the Technical regulations on medical products, approved by the CMU dated 02.10.2013 № 753</i>
Номер та термін дії сертифіката відповідності: <i>Number and validity of the Certificate of conformity:</i>	Сертифікат відповідності № PR.772-19 Видання №2 від 23.12.2021, дійсний до 30.06.2024 <i>Certificate of conformity № PR.772-19 Version №2 dated 23.12.2021, is valid till 30.06.2024</i>
Призначений орган з оцінки відповідності та його ідентифікаційний код: <i>Conformity assessment</i>	ТОВ «УКРАЇНСЬКИЙ НАУКОВИЙ ІНСТИТУТ СЕРТИФІКАЦІЇ», ідентифікаційний код № UA.TR.116 <i>The Ukrainian Scientific Institute of Certification, Limited Liability Company, identification number: UA.TR.116</i> 

body with its
identification number:

Балтон Сп. з о.о. декларує виконання основних вимог до медичних виробів, згідно Додатку 1, Технічного регламенту, щодо медичних виробів №753 (від 2 жовтня 2013 року).

Balton Sp. z o.o. declares the fulfillment of the essential requirements for a medical product in accordance to Annex 1 of the Technical Regulation of medical products No. 753 (dated October 2, 2013)

**Особа, відповідальна за
дотримання регуляторних
вимог Компанії Balton Sp. z o.o.
Ольга КАПІТОНОВА**

24-12-2021
(data/date)


(підпис/signature)

*Person responsible for
regulatory compliance
in the Balton Sp. z o.o.
Olga Kapitonova*

BALTON Sp. z o.o.
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Копія.
Згідно з оригіналом.
Сторожук Я.О.



Annex 1

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2.	Назва медичного виробу на українській мові / Назва медичного виробу на англійській мові : <i>Name of medical device on Ukrainian language / Name of medical device on English language :</i> Саморозширюючий стент для периферичних судин ДРЕГОН з системою доставки / Peripheral self-expanding stent DRAGON with delivery system Клас безпеки/Class of risk : IIb Загальний каталожний номер / General catalog number : ZSNP, ZSNP_R Каталожні номери / Catalog numbers: ZSNP4X201880, ZSNP4X301880, ZSNP4X401880, ZSNP4X501880, ZSNP4X601880, ZSNP4X701880, ZSNP4X801880, ZSNP4X901880, ZSNP4X1001880, ZSNP4X1101880, ZSNP4X1201880, ZSNP4X1501880, ZSNP4X2001880, ZSNP4X2018100, ZSNP4X3018100, ZSNP4X4018100, ZSNP4X5018100, ZSNP4X6018100, ZSNP4X7018100, ZSNP4X8018100, ZSNP4X9018100, ZSNP4X10018100, ZSNP4X11018100, ZSNP4X12018100, ZSNP4X15018100, ZSNP4X20018100, ZSNP4X2018120, ZSNP4X3018120, ZSNP4X4018120, ZSNP4X5018120, ZSNP4X6018120, ZSNP4X7018120, ZSNP4X8018120, ZSNP4X9018120, ZSNP4X10018120, ZSNP4X11018120, ZSNP4X12018120, ZSNP4X15018120, ZSNP4X20018120, ZSNP4X2018135, ZSNP4X3018135, ZSNP4X4018135, ZSNP4X5018135, ZSNP4X6018135, ZSNP4X7018135, ZSNP4X8018135, ZSNP4X9018135, ZSNP4X10018135, ZSNP4X11018135, ZSNP4X12018135, ZSNP4X15018135, ZSNP4X20018135, ZSNP4X203580, ZSNP4X303580, ZSNP4X403580, ZSNP4X503580, ZSNP4X603580, ZSNP4X703580, ZSNP4X803580, ZSNP4X903580, ZSNP4X1003580, ZSNP4X1103580, ZSNP4X1203580, ZSNP4X1503580, ZSNP4X2003580, ZSNP4X2035100, ZSNP4X3035100, ZSNP4X4035100, ZSNP4X5035100, ZSNP4X6035100, ZSNP4X7035100, ZSNP4X8035100, ZSNP4X9035100, ZSNP4X10035100, ZSNP4X11035100, ZSNP4X12035100, ZSNP4X15035100, ZSNP4X20035100, ZSNP4X2035120, ZSNP4X3035120, ZSNP4X4035120, ZSNP4X5035120, ZSNP4X6035120, ZSNP4X7035120, ZSNP4X8035120, ZSNP4X9035120, ZSNP4X10035120, ZSNP4X11035120, ZSNP4X12035120, ZSNP4X15035120, ZSNP4X20035120, ZSNP4X2035135, ZSNP4X3035135, ZSNP4X4035135, ZSNP4X5035135, ZSNP4X6035135, ZSNP4X7035135, ZSNP4X8035135, ZSNP4X9035135, ZSNP4X10035135, ZSNP4X11035135, ZSNP4X12035135, ZSNP4X15035135, ZSNP4X20035135, ZSNP5X201880, ZSNP5X301880, ZSNP5X401880, ZSNP5X501880, ZSNP5X601880, ZSNP5X701880, ZSNP5X801880, ZSNP5X901880, ZSNP5X1001880, ZSNP5X1101880, ZSNP5X1201880, ZSNP5X1501880, ZSNP5X2001880, ZSNP5X2018100, ZSNP5X3018100, ZSNP5X4018100, ZSNP5X5018100, ZSNP5X6018100, ZSNP5X7018100, ZSNP5X8018100, ZSNP5X9018100, ZSNP5X10018100, ZSNP5X11018100, ZSNP5X12018100, ZSNP5X15018100, ZSNP5X20018100, ZSNP5X2018120, ZSNP5X3018120, ZSNP5X4018120, ZSNP5X5018120, ZSNP5X6018120, ZSNP5X7018120, ZSNP5X8018120, ZSNP5X9018120, ZSNP5X10018120, ZSNP5X11018120, ZSNP5X12018120, ZSNP5X15018120,

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3.	Назва медичного виробу на українській мові / Назва медичного виробу на англійській мові : <i>Name of medical device on Ukrainian language / Name of medical device on English language :</i> Стент кобальто-хромовий для ниркових судин НЕФРО-Сі з системою доставки / COBALT-CHROMIUM STENTS FOR RENAL VESSELS NEFRO C WITH DELIVERY SYSTEM <i>Клас безпеки/Class of risk :</i> IIб <i>Загальний каталожний номер / General catalog number :</i> ZSTN_C <i>Каталожні номери / Catalog number :</i> ZSTN5x814140C, ZSTN5x1014140C, ZSTN5x1214140C, ZSTN5x1414140C, ZSTN5x1614140C, ZSTN5x1814140C, ZSTN5x2014140C, ZSTN5x2214140C, ZSTN5x2514140C, ZSTN6x1014140C, ZSTN6x1214140C, ZSTN6x1414140C, ZSTN6x1614140C, ZSTN6x1814140C, ZSTN6x2014140C, ZSTN6x2214140C, ZSTN6x2514140C, ZSTN7x1214140C, ZSTN7x1414140C, ZSTN7x1614140C, ZSTN7x1814140C, ZSTN7x2014140C, ZSTN7x2214140C, ZSTN7x2514140C
4.	Назва медичного виробу на українській мові / Назва медичного виробу на англійській мові : <i>Name of medical device on Ukrainian language / Name of medical device on English language :</i> Стент кобальто-хромовий для периферичних судин НЕПТУН-Сі з системою доставки Ар-Екс / O-Ті-Дабл'ю / COBALT-CHROMIUM STENT FOR PERIPHERAL VESSELS NEPTUN C WITH DELIVERY SYSTEM RX/OTW <i>Клас безпеки/Class of risk :</i> IIб <i>Загальний каталожний номер / General catalog number :</i> ZSTPCRX, ZSTPCOTW <i>Каталожні номери / Catalog number :</i> ZSTPCRX2x0814140, ZSTPCRX2x1014140, ZSTPCRX2x1214140, ZSTPCRX2x1514140, ZSTPCRX2x1814140, ZSTPCRX2x2214140, ZSTPCRX2x2514140, ZSTPCRX2x2914140, ZSTPCRX2x3414140, ZSTPCRX2x3614140, ZSTPCRX2x3814140, ZSTPCRX2x4014140, ZSTPCRX2.25x0814140, ZSTPCRX2.25x1014140, ZSTPCRX2.25x1214140, ZSTPCRX2.25x1514140, ZSTPCRX2.25x1814140, ZSTPCRX2.25x2214140, ZSTPCRX2.25x2514140, ZSTPCRX2.25x2914140, ZSTPCRX2.25x3414140, ZSTPCRX2.25x3614140, ZSTPCRX2.25x3814140, ZSTPCRX2.25x4014140, ZSTPCRX2.50x0814140, ZSTPCRX2.50x1014140, ZSTPCRX2.50x1214140, ZSTPCRX2.50x1514140, ZSTPCRX2.50x1814140, ZSTPCRX2.50x2214140, ZSTPCRX2.50x2514140, ZSTPCRX2.50x2914140, ZSTPCRX2.50x3414140, ZSTPCRX2.50x3614140, ZSTPCRX2.50x3814140, ZSTPCRX2.50x4014140, ZSTPCRX2.75x0814140, ZSTPCRX2.75x1014140, ZSTPCRX2.75x1214140, ZSTPCRX2.75x1514140, ZSTPCRX2.75x1814140, ZSTPCRX2.75x2214140, ZSTPCRX2.75x2514140, ZSTPCRX2.75x2914140, ZSTPCRX2.75x3414140, ZSTPCRX2.75x3614140, ZSTPCRX2.75x3814140, ZSTPCRX2.75x4014140, ZSTPCRX3x0814140, ZSTPCRX3x1014140, ZSTPCRX3x1214140, ZSTPCRX3x1514140, ZSTPCRX3x1814140, ZSTPCRX3x2214140, ZSTPCRX3x2514140, ZSTPCRX3x2914140, ZSTPCRX3x3414140, ZSTPCRX3x3614140, ZSTPCRX3x3814140, ZSTPCRX3x4014140, ZSTPCRX3.25x0814140, ZSTPCRX3.25x1014140, ZSTPCRX3.25x1214140, ZSTPCRX3.25x1514140, ZSTPCRX3.25x1814140, ZSTPCRX3.25x2214140, ZSTPCRX3.25x2514140, ZSTPCRX3.25x2914140, ZSTPCRX3.25x3414140, ZSTPCRX3.25x3614140,

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5.	Назва медичного виробу на українській мові / Назва медичного виробу на англійській мові : <i>Name of medical device on Ukrainian language / Name of medical device on English language :</i> Катетер для периферичної ангіопластики ЛЮБІК / ЛЮБІК, швидка заміна / PERIPHERAL ANGIOPLASTY CATHETER LOVIX / PERIPHERAL ANGIOPLASTY CATHETERS LOVIX , Rapid Exchange <i>Клас безпеки/Class of risk :</i> IIb <i>Загальний каталожний номер / General catalog number :</i> PBA, PBARX <i>Каталожні номери / Catalog number :</i> PBA1.5x201880, PBA1.5x2018100, PBA1.5x2018110, PBA1.5x2018120, PBA1.5x2018135, PBA1.5x2018170, PBA1.5x251880, PBA1.5x2518100, PBA1.5x2518110, PBA1.5x2518120, PBA1.5x2518135, PBA1.5x2518170, PBA1.5x301880, PBA1.5x3018100, PBA1.5x3018110, PBA1.5x3018120, PBA1.5x3018135, PBA1.5x3018170, PBA1.5x351880, PBA1.5x3518100, PBA1.5x3518110, PBA1.5x3518120, PBA1.5x3518135, PBA1.5x3518170, PBA1.5x401880, PBA1.5x4018100, PBA1.5x4018110, PBA1.5x4018120, PBA1.5x4018135, PBA1.5x4018170, PBA1.5x451880, PBA1.5x4518100, PBA1.5x4518110, PBA1.5x4518120, PBA1.5x4518135, PBA1.5x4518170, PBA1.5x501880, PBA1.5x5018100, PBA1.5x5018110, PBA1.5x5018120, PBA1.5x5018135, PBA1.5x5018170, PBA1.5x551880, PBA1.5x5518100, PBA1.5x5518110, PBA1.5x5518120, PBA1.5x5518135, PBA1.5x5518170, PBA1.5x601880, PBA1.5x6018100, PBA1.5x6018110, PBA1.5x6018120, PBA1.5x6018135, PBA1.5x6018170, PBA1.5x651880, PBA1.5x6518100, PBA1.5x6518110, PBA1.5x6518120, PBA1.5x6518135, PBA1.5x6518170, PBA1.5x701880, PBA1.5x7018100, PBA1.5x7018110, PBA1.5x7018120, PBA1.5x7018135, PBA1.5x7018170, PBA1.5x751880, PBA1.5x7518100, PBA1.5x7518110, PBA1.5x7518120, PBA1.5x7518135, PBA1.5x7518170, PBA1.5x801880, PBA1.5x8018100, PBA1.5x8018110, PBA1.5x8018120, PBA1.5x8018135, PBA1.5x8018170, PBA1.5x851880, PBA1.5x8518100, PBA1.5x8518110, PBA1.5x8518120, PBA1.5x8518135, PBA1.5x8518170, PBA1.5x901880, PBA1.5x9018100, PBA1.5x9018110, PBA1.5x9018120, PBA1.5x9018135, PBA1.5x9018170, PBA1.5x951880, PBA1.5x9518100, PBA1.5x9518110, PBA1.5x9518120, PBA1.5x9518135, PBA1.5x9518170, PBA1.5x1001880, PBA1.5x10018100, PBA1.5x10018110, PBA1.5x10018120, PBA1.5x10018135, PBA1.5x10018170, PBA1.5x202580, PBA1.5x2025100, PBA1.5x2025110, PBA1.5x2025120, PBA1.5x2025135, PBA1.5x2025170, PBA1.5x252580, PBA1.5x2525100, PBA1.5x2525110, PBA1.5x2525120, PBA1.5x2525135, PBA1.5x2525170, PBA1.5x302580, PBA1.5x3025100, PBA1.5x3025110, PBA1.5x3025120, PBA1.5x3025135, PBA1.5x3025170, PBA1.5x352580, PBA1.5x3525100, PBA1.5x3525110, PBA1.5x3525120, PBA1.5x3525135, PBA1.5x3525170, PBA1.5x402580, PBA1.5x4025100, PBA1.5x4025110, PBA1.5x4025120, PBA1.5x4025135, PBA1.5x4025170, PBA1.5x452580, PBA1.5x4525100, PBA1.5x4525110, PBA1.5x4525120, PBA1.5x4525135, PBA1.5x4525170, PBA1.5x502580, PBA1.5x5025100, PBA1.5x5025110, PBA1.5x5025120, PBA1.5x5025135, PBA1.5x5025170, PBA1.5x552580, PBA1.5x5525100, PBA1.5x5525110, PBA1.5x5525120, PBA1.5x5525135, PBA1.5x5525170, PBA1.5x602580, PBA1.5x6025100, PBA1.5x6025110, PBA1.5x6025120, PBA1.5x6025135, PBA1.5x6025170, PBA1.5x652580, PBA1.5x6525100, PBA1.5x6525110, PBA1.5x6525120, PBA1.5x6525135, PBA1.5x6525170, PBA1.5x702580, PBA1.5x7025100, PBA1.5x7025110, PBA1.5x7025120, PBA1.5x7025135, PBA1.5x7025170, PBA1.5x752580, PBA1.5x7525100, PBA1.5x7525110, PBA1.5x7525120, PBA1.5x7525135, PBA1.5x7525170, PBA1.5x802580, PBA1.5x8025100, PBA1.5x8025110, PBA1.5x8025120, PBA1.5x8025135, PBA1.5x8025170, PBA1.5x852580, PBA1.5x8525100, PBA1.5x8525110, PBA1.5x8525120, PBA1.5x8525135, PBA1.5x8525170, PBA1.5x902580, PBA1.5x9025100, PBA1.5x9025110, PBA1.5x9025120, PBA1.5x9025135, PBA1.5x9025170, PBA1.5x952580, PBA1.5x9525100, PBA1.5x9525110, PBA1.5x9525120, PBA1.5x9525135, PBA1.5x9525170, PBA1.5x1002580, PBA1.5x10025100, PBA1.5x10025110, PBA1.5x10025120, PBA1.5x10025135, PBA1.5x10025170, PBA1.5x1202580, PBA1.5x12025100, PBA1.5x12025110, PBA1.5x12025120, PBA1.5x12025135, PBA1.5x12025170, PBA1.5x1502580, PBA1.5x15025100, PBA1.5x15025110, PBA1.5x15025120, PBA1.5x15025135, PBA1.5x15025170, PBA1.5x2002580, PBA1.5x20025100, PBA1.5x20025110, PBA1.5x20025120, PBA1.5x20025135, PBA1.5x20025170, PBA1.5x2502580, PBA1.5x25025100, PBA1.5x25025110, PBA1.5x25025120, PBA1.5x25025135, PBA1.5x25025170, PBA1.5x201880, PBA1.5x2018100, PBA1.5x2018110, PBA1.5x2018120, PBA1.5x2018135, PBA1.5x2018170, PBA1.5x251880, PBA1.5x2518100, PBA1.5x2518110, PBA1.5x2518120, PBA1.5x2518135, PBA1.5x2518170, PBA1.5x301880, PBA1.5x3018100, PBA1.5x3018110, PBA1.5x3018120, PBA1.5x3018135, PBA1.5x3018170, PBA1.5x351880, PBA1.5x3518100, PBA1.5x3518110, PBA1.5x3518120, PBA1.5x3518135, PBA1.5x3518170, PBA1.5x401880, PBA1.5x4018100, PBA1.5x4018110, PBA1.5x4018120, PBA1.5x4018135, PBA1.5x4018170, PBA1.5x451880, PBA1.5x4518100, PBA1.5x4518110, PBA1.5x4518120, PBA1.5x4518135, PBA1.5x4518170, PBA1.5x501880, PBA1.5x5018100, PBA1.5x5018110, PBA1.5x5018120, PBA1.5x5018135, PBA1.5x5018170, PBA1.5x551880, PBA1.5x5518100, PBA1.5x5518110, PBA1.5x5518120, PBA1.5x5518135, PBA1.5x5518170.

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6.	Назва медичного виробу на українській мові / Назва медичного виробу на англійській мові : <i>Name of medical device on Ukrainian language / Name of medical device on English language :</i> Мікросфери ЕМБОКІУР / EMBOCURE MICROSPHERES <i>Клас безпеки/Class of risk :</i> IIb <i>Загальний каталожний номер / General catalog number :</i> MEC <i>Каталожні номери / Catalog number :</i> MEC50, MEC90, MEC125, MEC250, MEC500, MEC710, MEC900
7.	Назва медичного виробу на українській мові / Назва медичного виробу на англійській мові : <i>Name of medical device on Ukrainian language / Name of medical device on English language :</i> Мікросфери ЕМБОКІУР ПЛЮС / EMBOCURE PLUS MICROSPHERES <i>Клас безпеки/Class of risk :</i> IIb <i>Загальний каталожний номер / General catalog number :</i> MEC_P <i>Каталожні номери / Catalog number :</i> MEC50P, MEC90P, MEC125P, MEC250P, MEC500P, MEC710P, MEC900P

**Особа, відповідальна за
дотримання регуляторних
вимог Компанії Balton Sp. z o.o.
Ольга КАПІТОНОВА**

24-12-2021
(дата/date)


(підпис/signature)

*Person responsible for
regulatory compliance
in the Balton Sp. z o.o.
Olga Kapitonova*

BALTON Sp. z o.o.
POLAND
 00-496 Warsaw, 7 Nowy Świat Street, apt 14
 tel. (48-22) 579 44 20; tel./fax: (48-22) 621 58 14
 tel. (48-22) 597 44 10; tel./fax: (48-22) 597 44 44

Копія.
Згідно з оригіналом.
Сторожук Я.О.



**Декларація відповідності
медичних виробів № 003/2019**
*Declaration of conformity
of medical products № 003/2019*

Загальна назва виробів: <i>Common name of medical devices:</i>	Комплекти для епідуральної анестезії, комплекти комбіновані для епідурально-спинальної анестезії, катетери епідуральні, комплекти для спинальної анестезії, голки для спинальної анестезії, стенти для коронарних судин, стенти для коронарних судин з сиролімусом, катетери для вальвулопластики, нейропротекційні пристрої, комплекти для внутрішньоаортальної контрпульсації, стенти для периферичних судин з сиролімусом, саморозширні стенти для сонної артерії, біполярні електроди для тимчасової кардіостимуляції, катетери коронарні для ангіопластики, катетери для периферичної ангіопластики з паклітакселем, провідники з гідрофільним покриттям, набори для закриття відкритого овального вікна, комплекти для катетеризації великих судин, катетери для катетеризації великих судин, катетери для ангіографії, внутрішньосудинні катетери для видалення чужорідних тіл, механічний пристрій для тромбектомії. <i>Epidural anaesthesia sets, combined epidural-spinal anaesthesia sets, epidural catheters, spinal anaesthesia block sets, spinal anaesthesia needles, coronary stents, sirolimus eluting coronary stents, valvuloplasty catheters, neuroprotection systems, intra-aortic balloon catheter sets, sirolimus eluting peripheral stents, self-expanding carotid stents, temporary transvenous bipolar pacing electrodes, coronary angioplasty catheters, paclitaxel coated peripheral angioplasty balloon catheters, guide wires with hydrophilic coating, sets for closure of patent foramen ovale, large vessels catheterization sets, large vessels catheterization catheters, catheters for angiography, endovascular catheters for retrieval of foreign bodies, mechanical thrombectomy device.</i>
Перелік виробів: <i>List of products:</i>	Дивіться у Додатку №1 <i>See Annex 1</i>
Виробник: <i>Manufacturer:</i>	Балтон Сп. з о.о., вул. Нови Свят, 7/14, 00-496, Варшава, Польща <i>Balton Sp. z o.o., address: Warsaw (P.C. 00-496) 7/14 Nowy Swiat Street</i>
Уповноважений представник: <i>Authorized representative:</i>	ТОВ «МЕД-ІМПОРТ», м. Київ, вул. Предславинська, буд. 57, кв. 78, індекс 03150, код ЄДРПОУ 42844275, тел.: +380 97 100 00 62 <i>Med-Import LLC, address: Kyiv, Ukraine 03150, Predslavynska street, 57, app. 78, identification code of enterprise: 42844275, Tel. +380 97 100 00 62</i> <i>Згідно з оригіналом.</i> <i>Сторожук Я.О.</i>
Класифікація: <i>Classification:</i>	Згідно Додатка 2 Технічного Регламенту щодо медичних виробів, затвердженого постановою КМУ від 02.10.2013 № 753, клас потенційного ризику застосування III

Процедура оцінки відповідності: <i>Conformity Assessment Route:</i> Номер та термін дії сертифіката відповідності і сертифіката перевірки проекту: <i>Number and validity of the Certificate of conformity and Design examination certificate:</i> Призначений орган з оцінки відповідності та його ідентифікаційний код: <i>Conformity assessment body with its identification number:</i>	<i>According to Annex 2 of the Technical regulations on medical products, approved by the CMU dated 02.10.2013 № 753, class of potential use risk III</i> Додаток 3 Технічного регламенту щодо медичних виробів, затвердженого постановою КМУ від 02.10.2013 № 753 <i>Annex 3 of the Technical regulations on medical products, approved by the CMU dated 02.10.2013 № 753</i> Сертифікат відповідності № PR.772-19 Видання №2 від 23.12.2021, дійсний до 30.06.2024 <i>Certificate of conformity № PR.772-19 Version №2 dated 23.12.2021, is valid till 30.06.2024</i> Сертифікат перевірки проекту № PR.770-19 Видання №2 від 20.12.2021, дійсний до 30.06.2024 <i>Design examination certificate № PR.770-19 Version №2 dated 20.12.2021, is valid till 30.06.2024</i> ТОВ “УКРАЇНСЬКИЙ НАУКОВИЙ ІНСТИТУТ СЕРТИФІКАЦІЇ”, ідентифікаційний код № UA.TR.116 <i>The Ukrainian Scientific Institute of Certification, Limited Liability Company, identification number: UA.TR.116</i>
Балтон Сп. з о.о. декларує виконання основних вимог до медичних виробів, згідно Додатку 1, Технічного регламенту, щодо медичних виробів №753 (від 2 жовтня 2013 року). <i>Balton Sp. z o.o. declares the fulfillment of the essential requirements for a medical product in accordance to Annex 1 of the Technical Regulation of medical products No. 753 (dated October 2, 2013)</i>	

Особа, відповідальна за дотримання регуляторних вимог Компанії Balton Sp. z o.o.
Ольга КАШТОНОВА

Person responsible for regulatory compliance in the Balton Sp. z o.o.
Olga Kapitonova

24-12-2021
(дата/date)


(підпис/signature)

Копія.
Згідно з оригіналом.
Сторожук Я.О.





Декларація про відповідність № 003/2019

Declaration of conformity № 003/2019

Додаток 1

Annex 1

№ з/п	Інформація про виріб / Product information
1.	Назва медичного виробу на українській мові / Назва медичного виробу на англійській мові : <i>Name of medical device on Ukrainian language / Name of medical device on English language :</i> Комплект для епідуральної анестезії, розширений / EPIDURAL ANAESTHESIA SET, advanced Клас безпеки/Class of risk : III Загальний каталожний номер / General catalog number : ZZOR, ZZOR_S, ZZOR_EM, ZZOR_SEM Каталожні номери / Catalog numbers: ZZOR19G, ZZOR18G, ZZOR17G, ZZOR16G, ZZOR19GS, ZZOR18GS, ZZOR17GS, ZZOR16GS, ZZOR16GEM, ZZOR17GEM, ZZOR18GEM, ZZOR19GEM, ZZOR16GSEM, ZZOR17GSEM, ZZOR18GSEM, ZZOR19GSEM
2.	Назва медичного виробу на українській мові / Назва медичного виробу на англійській мові : <i>Name of medical device on Ukrainian language / Name of medical device on English language :</i> Комплект для епідуральної анестезії, малий / EPIDURAL ANAESTHESIA SET, small Клас безпеки/Class of risk : III Загальний каталожний номер / General catalog number : ZZOM, ZZOM_S, ZZOM_SN, ZZOM_SSN, ZZOM_EM, ZZOM_SEM, ZZOM_SNEM, ZZOM_SSNEM Каталожні номери / Catalog numbers: ZZOM19G, ZZOM18G, ZZOM17G, ZZOM16G, ZZOM19GS, ZZOM18GS, ZZOM17GS, ZZOM16GS, ZZOM19GSN, ZZOM18GSN, ZZOM17GSN, ZZOM16GSN, ZZOM19GSSN, ZZOM18GSSN, ZZOM17GSSN, ZZOM16GSSN, ZZOM16GEM, ZZOM17GEM, ZZOM18GEM, ZZOM19GEM, ZZOM16GSEM, ZZOM17GSEM, ZZOM18GSEM, ZZOM19GSEM, ZZOM16GSNEM, ZZOM17GSNEM, ZZOM18GSNEM, ZZOM19GSNEM, ZZOM16GSSNEM, ZZOM17GSSNEM, ZZOM18GSSNEM, ZZOM19GSSNEM
3.	Назва медичного виробу на українській мові / Назва медичного виробу на англійській мові : <i>Name of medical device on Ukrainian language / Name of medical device on English language :</i> Комплект для епідуральної анестезії з аксесуарами для спинальної та комбінованої анестезії / EPIDURAL ANAESTHESIA SET with accessories for spinal and combined anesthesia Клас безпеки/Class of risk : III Загальний каталожний номер / General catalog number : ZZOR_D, ZZOR_SD Каталожні номери / Catalog numb : ZZOR19GD, ZZOR18GD, ZZOR17GD, ZZOR16GD, ZZOR19GSD, ZZOR18GSD, ZZOR17GSD, ZZOR16GSD Копія. Згідно з оригіналом. Сторожук Я.О.

Сторожук Ярослав Олегович
Ідентифікаційний номер 2919120173
Інженер медичного обладнання

	ZSTC3.00x2914CFSP, ZSTC3.00x3414CFSP, ZSTC3.00x3614CFSP, ZSTC3.00x3814CFSP, ZSTC3.00x4014CFSP, ZSTC3.25x0814CFSP, ZSTC3.25x1014CFSP, ZSTC3.25x1214CFSP, ZSTC3.25x1514CFSP, ZSTC3.25x1814CFSP, ZSTC3.25x2214CFSP, ZSTC3.25x2514CFSP, ZSTC3.25x2914CFSP, ZSTC3.25x3414CFSP, ZSTC3.25x3614CFSP, ZSTC3.25x3814CFSP, ZSTC3.25x4014CFSP, ZSTC3.50x0814CFSP, ZSTC3.50x1014CFSP, ZSTC3.50x1214CFSP, ZSTC3.50x1514CFSP, ZSTC3.50x1814CFSP, ZSTC3.50x2214CFSP, ZSTC3.50x2514CFSP, ZSTC3.50x2914CFSP, ZSTC3.50x3414CFSP, ZSTC3.50x3614CFSP, ZSTC3.50x3814CFSP, ZSTC3.50x4014CFSP, ZSTC3.75x0814CFSP, ZSTC3.75x1014CFSP, ZSTC3.75x1214CFSP, ZSTC3.75x1514CFSP, ZSTC3.75x1814CFSP, ZSTC3.75x2214CFSP, ZSTC3.75x2514CFSP, ZSTC3.75x2914CFSP, ZSTC3.75x3414CFSP, ZSTC3.75x3614CFSP, ZSTC3.75x3814CFSP, ZSTC3.75x4014CFSP, ZSTC4.00x0814CFSP, ZSTC4.00x1014CFSP, ZSTC4.00x1214CFSP, ZSTC4.00x1514CFSP, ZSTC4.00x1814CFSP, ZSTC4.00x2214CFSP, ZSTC4.00x2514CFSP, ZSTC4.00x2914CFSP, ZSTC4.00x3414CFSP, ZSTC4.00x3614CFSP, ZSTC4.00x3814CFSP, ZSTC4.00x4014CFSP, ZSTC4.50x0814CFSP, ZSTC4.50x1014CFSP, ZSTC4.50x1214CFSP, ZSTC4.50x1514CFSP, ZSTC4.50x1814CFSP, ZSTC4.50x2214CFSP, ZSTC4.50x2514CFSP, ZSTC4.50x2914CFSP, ZSTC4.50x3414CFSP, ZSTC4.50x3614CFSP, ZSTC4.50x3814CFSP, ZSTC4.50x4014CFSP, ZSTC5.00x0814CFSP, ZSTC5.00x1014CFSP, ZSTC5.00x1214CFSP, ZSTC5.00x1514CFSP, ZSTC5.00x1814CFSP, ZSTC5.00x2214CFSP, ZSTC5.00x2514CFSP, ZSTC5.00x2914CFSP, ZSTC5.00x3414CFSP, ZSTC5.00x3614CFSP, ZSTC5.00x3814CFSP, ZSTC5.00x4014CFSP.
14.	Назва медичного виробу на українській мові / Назва медичного виробу на англійській мові : <i>Name of medical device on Ukrainian language / Name of medical device on English language :</i> Стент з сиролімутом для коронарних судин ПРОЛІМ з системою доставки / SIROLIMUS ELUTING CORONARY STENT PROLIM WITH DELIVERY SYSTEM RX <i>Клас безпеки/Class of risk :</i> III <i>Загальний каталожний номер / General catalog number :</i> ZSTC_SF <i>Каталожні номери / Catalog numbers:</i> ZSTC2.00x0814SF, ZSTC2.00x1014SF, ZSTC2.00x1214SF, ZSTC2.00x1514SF, ZSTC2.00x1814SF, ZSTC2.00x2214SF, ZSTC2.00x2514SF, ZSTC2.00x2914SF, ZSTC2.00x3414SF, ZSTC2.00x3614SF, ZSTC2.00x3814SF, ZSTC2.00x4014SF, ZSTC2.25x0814SF, ZSTC2.25x1014SF, ZSTC2.25x1214SF, ZSTC2.25x1514SF, ZSTC2.25x1814SF, ZSTC2.25x2214SF, ZSTC2.25x2514SF, ZSTC2.25x2914SF, ZSTC2.25x3414SF, ZSTC2.25x3614SF, ZSTC2.25x3814SF, ZSTC2.25x4014SF, ZSTC2.50x0814SF, ZSTC2.50x1014SF, ZSTC2.50x1214SF, ZSTC2.50x1514SF, ZSTC2.50x1814SF, ZSTC2.50x2214SF, ZSTC2.50x2514SF, ZSTC2.50x2914SF, ZSTC2.50x3414SF, ZSTC2.50x3614SF, ZSTC2.50x3814SF, ZSTC2.50x4014SF, ZSTC2.75x0814SF, ZSTC2.75x1014SF, ZSTC2.75x1214SF, ZSTC2.75x1514SF, ZSTC2.75x1814SF, ZSTC2.75x2214SF, ZSTC2.75x2514SF, ZSTC2.75x2914SF, ZSTC2.75x3414SF, ZSTC2.75x3614SF, ZSTC2.75x3814SF, ZSTC2.75x4014SF, ZSTC3.00x0814SF, ZSTC3.00x1014SF, ZSTC3.00x1214SF, ZSTC3.00x1514SF, ZSTC3.00x1814SF, ZSTC3.00x2214SF, ZSTC3.00x2514SF, ZSTC3.00x2914SF, ZSTC3.00x3414SF, ZSTC3.00x3614SF, ZSTC3.00x3814SF, ZSTC3.00x4014SF, ZSTC3.25x0814SF, ZSTC3.25x1014SF, ZSTC3.25x1214SF, ZSTC3.25x1514SF, ZSTC3.25x1814SF, ZSTC3.25x2214SF, ZSTC3.25x2514SF, ZSTC3.25x2914SF, ZSTC3.25x3414SF, ZSTC3.25x3614SF, ZSTC3.25x3814SF, ZSTC3.25x4014SF, ZSTC3.50x0814SF, ZSTC3.50x1014SF, ZSTC3.50x1214SF, ZSTC3.50x1514SF, ZSTC3.50x1814SF, ZSTC3.50x2214SF, ZSTC3.50x2514SF, ZSTC3.50x2914SF, ZSTC3.50x3414SF, ZSTC3.50x3614SF, ZSTC3.50x3814SF, ZSTC3.50x4014SF, ZSTC3.75x0814SF, ZSTC3.75x1014SF, ZSTC3.75x1214SF, ZSTC3.75x1514SF, ZSTC3.75x1814SF, ZSTC3.75x2214SF, ZSTC3.75x2514SF, ZSTC3.75x2914SF, ZSTC3.75x3414SF, ZSTC3.75x3614SF, ZSTC3.75x3814SF, ZSTC3.75x4014SF, ZSTC4.00x0814SF, ZSTC4.00x1014SF, ZSTC4.00x1214SF, ZSTC4.00x1514SF, ZSTC4.00x1814SF, ZSTC4.00x2214SF, ZSTC4.00x2514SF, ZSTC4.00x2914SF, ZSTC4.00x3414SF, ZSTC4.00x3614SF, ZSTC4.00x3814SF, ZSTC4.00x4014SF, ZSTC4.50x0814SF, ZSTC4.50x1014SF, ZSTC4.50x1214SF, ZSTC4.50x1514SF, ZSTC4.50x1814SF, ZSTC4.50x2214SF, ZSTC4.50x2514SF, ZSTC4.50x2914SF, ZSTC4.50x3414SF, ZSTC4.50x3614SF, ZSTC4.50x3814SF, ZSTC4.50x4014SF, ZSTC5.00x0814SF, ZSTC5.00x1014SF, ZSTC5.00x1214SF, ZSTC5.00x1514SF, ZSTC5.00x1814SF, ZSTC5.00x2214SF, ZSTC5.00x2514SF, ZSTC5.00x2914SF, ZSTC5.00x3414SF, ZSTC5.00x3614SF, ZSTC5.00x3814SF, ZSTC5.00x4014SF
15.	Назва медичного виробу на українській мові / Назва медичного виробу на англійській мові : <i>Name of medical device on Ukrainian language / Name of medical device on English language :</i> Стент коронарний кобальто-хромовий з сиролімутом для біфуркації коронарних судин БіОСС ЛІМ Сі з системою доставки / COBALT-CHROMIUM SIROLIMUS ELUTING CORONARY BIFURCATION STENT BiOSS LIM C WITH DELIVERY SYSTEM RAPID EXCHANGE <i>Клас безпеки/Class of risk :</i> III <i>Загальний каталожний номер / General catalog number :</i> ZSTB_CS <i>Каталожні номери / Catalog numbers:</i> ZSTB2.50X3.00X1514CS, ZSTB2.50X3.25X1514CS, ZSTB2.75X3.50X1514CS, ZSTB3.00X3.50X1514CS, ZSTB3.00X3.75X1514CS, ZSTB3.50X4.25X1514CS, ZSTB3.75X4.50X1514CS, ZSTB3.75X4.75X1514CS, ZSTB4.00X5.00X1514CS, ZSTB2.50X3.00X1614CS, ZSTB2.50X3.25X1614CS, ZSTB2.75X3.50X1614CS, ZSTB3.00X3.50X1614CS, ZSTB3.00X3.75X1614CS, ZSTB3.50X4.25X1614CS, ZSTB3.75X4.50X1614CS, ZSTB3.75X4.75X1614CS, ZSTB4.00X5.00X1614CS, ZSTB2.50X3.00X1814CS, ZSTB2.50X3.25X1814CS,

	ZSTB2.75X3.50X1814CS, ZSTB3.00X3.50X1814CS, ZSTB3.00X3.75X1814CS, ZSTB3.50X4.25X1814CS, ZSTB3.75X4.50X1814CS, ZSTB3.75X4.75X1814CS, ZSTB4.00X5.00X1814CS, ZSTB2.50X3.00X1914CS, ZSTB2.50X3.25X1914CS, ZSTB2.75X3.50X1914CS, ZSTB3.00X3.50X1914CS, ZSTB3.00X3.75X1914CS, ZSTB3.50X4.25X1914CS, ZSTB3.75X4.50X1914CS, ZSTB3.75X4.75X1914CS, ZSTB4.00X5.00X1914CS, ZSTB2.50X3.00X2314CS, ZSTB2.50X3.25X2314CS, ZSTB2.75X3.50X2314CS, ZSTB3.00X3.50X2314CS, ZSTB3.00X3.75X2314CS, ZSTB3.50X4.25X2314CS, ZSTB3.75X4.50X2314CS, ZSTB3.75X4.75X2314CS, ZSTB4.00X5.00X2314CS, ZSTB2.50X3.00X2414CS, ZSTB2.50X3.25X2414CS, ZSTB2.75X3.50X2414CS, ZSTB3.00X3.50X2414CS, ZSTB3.00X3.75X2414CS, ZSTB3.50X4.25X2414CS, ZSTB3.75X4.50X2414CS, ZSTB3.75X4.75X2414CS, ZSTB4.00X5.00X2414CS.
16.	Назва медичного виробу на українській мові / Назва медичного виробу на англійській мові : <i>Name of medical device on Ukrainian language / Name of medical device on English language :</i> Катетер для вальвулопластики ВАЛЬВЕР / VALVULOPLASTY CATHETER VALVER <i>Клас безпеки/Class of risk :</i> III <i>Загальний каталожний номер / General catalog number :</i> VALP, VAL, VALB <i>Каталожні номери / Catalog numbers:</i> VALP5X2070, VALP5X2570, VALP5X3070, VALP5X3570, VALP5X4070, VALP5X4570, VALP5X5070, VALP5X6070, VALP6X2070, VALP6X2570, VALP6X3070, VALP6X3570, VALP6X4070, VALP6X4570, VALP6X5070, VALP6X6070, VALP7X2070, VALP7X2570, VALP7X3070, VALP7X3570, VALP7X4070, VALP7X4570, VALP7X5070, VALP7X6070, VALP8X2070, VALP8X2570, VALP8X3070, VALP8X3570, VALP8X4070, VALP8X4570, VALP8X5070, VALP8X6070, VALP9X2070, VALP9X2570, VALP9X3070, VALP9X3570, VALP9X4070, VALP9X4570, VALP9X5070, VALP9X6070, VALP10X2070, VALP10X2570, VALP10X3070, VALP10X3570, VALP10X4070, VALP10X4570, VALP10X5070, VALP10X6070, VALP11X2070, VALP11X2570, VALP11X3070, VALP11X3570, VALP11X4070, VALP11X4570, VALP11X5070, VALP11X6070, VALP12X2070, VALP12X2570, VALP12X3070, VALP12X3570, VALP12X4070, VALP12X4570, VALP12X5070, VALP12X6070, VALP13X2070, VALP13X2570, VALP13X3070, VALP13X3570, VALP13X4070, VALP13X4570, VALP13X5070, VALP13X6070, VALP14X2070, VALP14X2570, VALP14X3070, VALP14X3570, VALP14X4070, VALP14X4570, VALP14X5070, VALP14X6070, VALP15X2070, VALP15X2570, VALP15X3070, VALP15X3570, VALP15X4070, VALP15X4570, VALP15X5070, VALP15X6070, VALP5X20110, VALP5X25110, VALP5X30110, VALP5X35110, VALP5X40110, VALP5X45110, VALP5X50110, VALP5X60110, VALP6X20110, VALP6X25110, VALP6X30110, VALP6X35110, VALP6X40110, VALP6X45110, VALP6X50110, VALP6X60110, VALP7X20110, VALP7X25110, VALP7X30110, VALP7X35110, VALP7X40110, VALP7X45110, VALP7X50110, VALP7X60110, VALP8X20110, VALP8X25110, VALP8X30110, VALP8X35110, VALP8X40110, VALP8X45110, VALP8X50110, VALP8X60110, VALP9X20110, VALP9X25110, VALP9X30110, VALP9X35110, VALP9X40110, VALP9X45110, VALP9X50110, VALP9X60110, VALP10X20110, VALP10X25110, VALP10X30110, VALP10X35110, VALP10X40110, VALP10X45110, VALP10X50110, VALP10X60110, VALP11X20110, VALP11X25110, VALP11X30110, VALP11X35110, VALP11X40110, VALP11X45110, VALP11X50110, VALP11X60110, VALP12X20110, VALP12X25110, VALP12X30110, VALP12X35110, VALP12X40110, VALP12X45110, VALP12X50110, VALP12X60110, VALP13X20110, VALP13X25110, VALP13X30110, VALP13X35110, VALP13X40110, VALP13X45110, VALP13X50110, VALP13X60110, VALP14X20110, VALP14X25110, VALP14X30110, VALP14X35110, VALP14X40110, VALP14X45110, VALP14X50110, VALP14X60110, VALP15X20110, VALP15X25110, VALP15X30110, VALP15X35110, VALP15X40110, VALP15X45110, VALP15X50110, VALP15X60110, VAL15X20110, VAL15X25110, VAL15X30110, VAL15X35110, VAL15X40110, VAL15X45110, VAL15X50110, VAL15X60110, VAL16X20110, VAL16X25110, VAL16X30110, VAL16X35110, VAL16X40110, VAL16X45110, VAL16X50110, VAL16X60110, VAL18X20110, VAL18X25110, VAL18X30110, VAL18X35110, VAL18X40110, VAL18X45110, VAL18X50110, VAL18X60110, VAL20X20110, VAL20X25110, VAL20X30110, VAL20X35110, VAL20X40110, VAL20X45110, VAL20X50110, VAL20X60110, VAL23X20110, VAL23X25110, VAL23X30110, VAL23X35110, VAL23X40110, VAL23X45110, VAL23X50110, VAL23X60110, VAL25X20110, VAL25X25110, VAL25X30110, VAL25X35110, VAL25X40110, VAL25X45110, VAL25X50110, VAL25X60110, VAL28X20110, VAL28X25110, VAL28X30110, VAL28X35110, VAL28X40110, VAL28X45110, VAL28X50110, VAL28X60110, VAL30X20110, VAL30X25110, VAL30X30110, VAL30X35110, VAL30X40110, VAL30X45110, VAL30X50110, VAL30X60110, VAL35X20110, VAL35X25110, VAL35X30110, VAL35X35110, VAL35X40110, VAL35X45110, VAL35X50110, VAL35X60110, VALB231823X40110, VALB252025X40110, VALB282328X40110, VALB312631X40110
17.	Назва медичного виробу на українській мові / Назва медичного виробу на англійській мові : <i>Name of medical device on Ukrainian language / Name of medical device on English language :</i> Нейропротекційний пристрій РОБІН (Ар-Екс) / Нейропротекційний пристрій РОБІН (О-Ті-Дабл'ю) / NEUROPROTECTION SYSTEM ROBIN RAPID EXCHANGE (RX) / NEUROPROTECTION SYSTEM ROBIN OVER THE WIRE (OTW) <i>Клас безпеки/Class of risk :</i> III <i>Загальний каталожний номер / General catalog number :</i> SDN_RX, SDN_RXS, SDN_RXM, SDN_RXSM, SDN_OTW, SDN_OTWS, SDN_OTWM, SDN_OTWSM <i>Каталожні номери / Catalog numbers:</i> SDN4RX, SDN4RXS, SDN4RXM, SDN4RXSM, SDN5RX, SDN5RXS, SDN5RXM, SDN5RXSM, SDN6RX, SDN6RXS, SDN6RXM, SDN6RXSM, SDN7RX, SDN7RXS, SDN7RXM, SDN7RXSM, SDN8RX, SDN8RXS, SDN8RXM, SDN8RXSM, SDN4OTW, SDN4OTWS, SDN4OTWM, SDN4OTWSM, SDN5OTW, SDN5OTWS, SDN5OTWM, SDN5OTWSM, SDN6OTW,

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Особа, відповідальна за
дотримання регуляторних
вимог Компанії Balton Sp. z o.o.
Ольга КАПІТОНОВА

24-12-2021
(дата/date)

[Signature]

(підпис/signature)

Person responsible for
regulatory compliance
in the Balton Sp. z o.o.
Olga Kapitonova

Копія.
Згідно з оригіналом.
Сторожук Я.О.

[Signature]

