



M.D.L. Srl  
 Via Tavani 1/a - 23014 - Delebio (So) - Italy  
 Tel (+39) 0342 / 692130 Fax (+39) 0342 / 691316  
 P.IVA e Cod. Fiscale 00656810140 Cod. Rea : 46278  
 e-mail: info@mdlsrl.com web:www.mdlsrl.com



**Certificate of Analysis**

**Product Information**

**Code:** PIP1810/50

**Description:** DISPOSABLE NEEDLE FOR BONE MARROW ASPIRATION 18Gx10/50mm

BATCH	MANUFACTURING DATE	EXPIRATION DATE	TRANSPORT DOC N.	STERILIZATION BATCH
2418AA	06/05/2024	30/04/2029	1159	24053105

Type of Test	Acceptance Criteria	Results	Test Date	Acceptance of results
Functional Test	In compliance to the manufacturer's specifications	Passed	14/06/2024	Accepted
Mechanical Test	In compliance to the manufacturer's specifications	Passed	14/06/2024	Accepted
Visive Test	In compliance to the manufacturer's specifications	Passed	14/06/2024	Accepted
Dimensional Test	In compliance to the manufacturer's specifications	Passed	14/06/2024	Accepted
Verification of Sterilization Parameters	Inside tolerances as for validation report issued in	Meet	14/06/2024	Accepted
Verification of Residual Ethylene Oxide	In compliance to ISO 10993-7	Meet	14/06/2024	Accepted
Verification of Packaging	In compliance to ISO 11807	Meet	14/06/2024	Accepted
Biocompatibility	In compliance to ISO 10993-1	Meet	14/06/2024	Accepted
Pyrogenicity	Apyrogene in compliance to current USP Chapter 181	Passed	14/06/2024	Accepted

Note: section marked as "N/A" indicate testing is not required for this product.  
 All lots manufactured are tested per the above criteria.  
 Throughout this document we confirm that this product has been released for sale based on the result of the applicable acceptance criteria as for the internal procedures.

Delebio, li 14/06/2024

**M.D.L. S.R.L.**  
 Il Legale Rappresentante  
 Dott. Marcello Dell'Oca



КОПИЯ ВЕРНА





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**Description:** DISPOSABLE NEEDLE FOR BONE MARROW ASPIRATION 18Gx10/50mm

BATCH	MANUFACTURING DATE	EXPIRATION DATE	TRANSPORT DOC N.	STERILIZATION BATCH
2412AA	22/04/2024	31/03/2029	1090	24052405

Type of Test	Acceptance Criteria	Results	Test Date	Acceptance of results
Functional Test	In compliance to the manufacturer's specifications	Passed	05/06/2024	Accepted
Mechanical Test	In compliance to the manufacturer's specifications	Passed	05/06/2024	Accepted
Visive Test	In compliance to the manufacturer's specifications	Passed	05/06/2024	Accepted
Dimensional Test	In compliance to the manufacturer's specifications	Passed	05/06/2024	Accepted
Verification of Sterilization Parameters	Inside tolerances as for validation report issued in	Meet	05/06/2024	Accepted
Verification of Residual Ethylene Oxide	In compliance to ISO 10993-7	Meet	05/06/2024	Accepted
Verification of Packaging	In compliance to ISO 11607	Meet	05/06/2024	Accepted
Biocompatibility	In compliance to ISO 10993-1	Meet	05/06/2024	Accepted
Pyrogenicity	Apyrogene in compliance to current USP Chapter 161	Passed	05/06/2024	Accepted

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Delebio, Il 05/06/2024



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BATCH	MANUFACTURING DATE	EXPIRATION DATE	TRANSPORT DOC N.	STERILIZATION BATCH
2413AA	22/04/2024	31/03/2029	1090	24051005

Type of Test	Acceptance Criteria	Results	Test Date	Acceptance of results
Functional Test	In compliance to the manufacturer's specifications	Passed	05/06/2024	Accepted
Mechanical Test	In compliance to the manufacturer's specifications	Passed	05/06/2024	Accepted
Visive Test	In compliance to the manufacturer's specifications	Passed	05/06/2024	Accepted
Dimensional Test	In compliance to the manufacturer's specifications	Passed	05/06/2024	Accepted
Verification of Sterilization Parameters	Inside tolerances as for validation report issued in	Meet	05/06/2024	Accepted
Verification of Residual Ethylene Oxide	In compliance to ISO 10993-7	Meet	05/06/2024	Accepted
Verification of Packaging	In compliance to ISO 11607	Meet	05/06/2024	Accepted
Biocompatibility	In compliance to ISO 10993-1	Meet	05/06/2024	Accepted
Pyrogenicity	Apyrogene in compliance to current USP Chapter 161	Passed	05/06/2024	Accepted

Note: section marked as "N/A" indicate testing is not required for this product.  
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Delebio, li 05/06/2024

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**Description:** DISPOSABLE NEEDLE FOR BONE MARROW ASPIRATION 18Gx10/50mm

BATCH	MANUFACTURING DATE	EXPIRATION DATE	TRANSPORT DOC N.	STERILIZATION BATCH
2410AA	08/04/2024	31/03/2029	1090	24050205

Type of Test	Acceptance Criteria	Results	Test Date	Acceptance of results
Functional Test	In compliance to the manufacturer's specifications	Passed	05/06/2024	Accepted
Mechanical Test	In compliance to the manufacturer's specifications	Passed	05/06/2024	Accepted
Visive Test	In compliance to the manufacturer's specifications	Passed	05/06/2024	Accepted
Dimensional Test	In compliance to the manufacturer's specifications	Passed	05/06/2024	Accepted
Verification of Sterilization Parameters	Inside tolerances as for validation report issued in	Meet	05/06/2024	Accepted
Verification of Residual Ethylene Oxide	In compliance to ISO 10993-7	Meet	05/06/2024	Accepted
Verification of Packaging	In compliance to ISO 11607	Meet	05/06/2024	Accepted
Biocompatibility	In compliance to ISO 10993-1	Meet	05/06/2024	Accepted
Pyrogenicity	Apyrogene in compliance to current USP Chapter 161	Passed	05/06/2024	Accepted

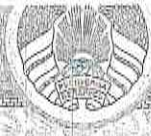
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Delebio, li 05/06/2024

**M.D.L. S.R.L.**  
 Il Legale Rappresentante  
 Dott. Marcello Dell'Oca







МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ БЕЛАРУСЬ

# РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ

№ ИМ-7.114483

Настоящее удостоверение выдано

**M.D.L. S.r.l., ИТАЛИЯ**

и является подтверждением того, что Министерством здравоохранения Республики Беларусь зарегистрированы

**Изделия для аспирации и биопсии: иглы для аспирации и биопсии костного мозга;; см. приложение, всего номеров регистрации - 5**

Тип: изделия медицинского назначения.

Производитель: **M.D.L. S.r.l., ИТАЛИЯ. Адрес: Via Tavani 1A, 23014, Delebio**

Производственная площадка: **M.D.L. S.r.l., ИТАЛИЯ. Адрес: Via Tavani 1A, 23014, Delebio**

и разрешены к производству, реализации и медицинскому применению на территории Республики Беларусь

**В соответствии с инструкцией по использованию**

Регистрационный номер: **Мн-7.119803/7.007-2306**

Регистрационное удостоверение не является обязательством к закупке данных изделий медицинского назначения.

Дата государственной регистрации:  
**29.08.2023 г.**

Действительно до:  
**бессрочно**

Заместитель Министра

**Б. Н. Андросюк**  
Ашманкевич ДД



*(Handwritten signature in blue ink)*

№ 0038124

# ПРИЛОЖЕНИЕ К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ № ИМ-7.114483

Всего наименований:

5

Страница: 2

Страниц: 5

Изготовитель: **M.D.L. S.r.l., ИТАЛИЯ**

№	Номер регистрации	Наименование, нормативный документ, код:
1	Мн-7.119803/7-007	<p>ИЗДЕЛИЯ ДЛЯ АСПИРАЦИИ И БИОПСИИ: ИГЛЫ ДЛЯ АСПИРАЦИИ И БИОПСИИ КОСТНОГО МОЗГА: 2306</p> <ul style="list-style-type: none"> <li>- игла PenBone (кат. № PI1410/75, PI1425/90, PI1435/100, PI1510/75, PI1525/90, PI1535/100, PI1610/75, PI1625/90, PI1635/100, PI1810/75, PI1825/90, PI1835/100)</li> <li>- игла PenBone Blu (кат. № PIP1410/50, PIP1430/70, PIP1455/95, PIP1510/50, PIP1520/60, PIP1530/70, PIP1555/95, PIP1610/50, PIP1630/70, PIP1655/95, PIP1810/50, PIP1830/70, PIP1835/72, PIP1855/95)</li> <li>- игла Ily (кат. № PIL1410/75, PIL1420/85, PIL1435/100, PIL1510/75, PIL1520/85, PIL1535/100, PIL1610/75, PIL1620/85, PIL1635/100, PIL1810/75, PIL1820/85, PIL1835/100)</li> <li>- игла IlyE (кат. № PILE1410/75, PILE1420/85, PILE1435/100, PILE1510/75, PILE1520/85, PILE1535/100, PILE1610/75, PILE1620/85, PILE1635/100, PILE1810/75, PILE1820/85, PILE1835/100)</li> <li>- игла OsteoJ, (кат. № PJ0810, PJ0815, PJ0910, PJ0915, PJ1110, PJ1115, PJ1306, PJ1307, PJ1309, PJ1310, PJ1315)</li> <li>- игла Harvest, (кат. № PJE0810, PJE0815, PJE0910, PJE0915, PJE1110, PJE1115, PJE1306, PJE1307, PJE1309, PJE1310, PJE1315)</li> <li>- игла PickUp, (кат. № PJT0810, PJT0815, PJT0910, PJT0915, PJT1110, PJT1115, PJT1306, PJT1307, PJT1309, PJT1310, PJT1315)</li> <li>- игла PressTo, (кат. № PS0810, PS0815, PS0910, PS0915, PS1110, PS1115, PS1306, PS1307, PS1309, PS1310, PS1315)</li> <li>- игла JamBlu, (кат. № PJK20810, PJK20815, PJK20910, PJK20915, PJK21110, PJK21115, PJK21306, PJK21307, PJK21309, PJK21310, PJK21315)</li> </ul>
2	Мн-7.119803/7-008	<p>ИЗДЕЛИЯ ДЛЯ АСПИРАЦИИ И БИОПСИИ: ИГЛЫ И НАБОРЫ ДЛЯ АСПИРАЦИИ И БИОПСИИ МЯГКИХ ТКАНЕЙ: 2306</p> <ul style="list-style-type: none"> <li>- игла Pallum Needle, совместимая с автоматическим биопсийным пистолетом Pallum и Magnum Bard®, (кат. № MGK11115, MGK11206, MGK11207, MGK112074, MGK112075, MGK11209, MGK11210, MGK11211, MGK112114, MGK11212, MGK11213, MGK11215, MGK11216, MGK11218, MGK11220, MGK11225, MGK11228, MGK11230, MGK11407, MGK114074, MGK114075, MGK11409, MGK11410, MGK11411, MGK114114, MGK11412, MGK11413, MGK11415, MGK11416, MGK11418, MGK11420, MGK11425, MGK11428, MGK11430, MGK11607, MGK116074, MGK116075, MGK11609, MGK11610, MGK11611, MGK116114, MGK11612, MGK11613, MGK11615, MGK11616, MGK11618, MGK11620, MGK11625, MGK11628, MGK11630, MGK11807, MGK118074, MGK118075, MGK11809, MGK11810, MGK11811, MGK11814, MGK11812, MGK11813, MGK11815, MGK11816, MGK11818, MGK11820, MGK11825, MGK11828, MGK11830, MGK12007, MGK120074, MGK120075, MGK12009, MGK12010, MGK12011, MGK12014, MGK12012, MGK12013, MGK12015, MGK12016, MGK12018, MGK12020, MGK12025, MGK12028, MGK12030, MGK121075, MGK12110, MGK12115, MGK12116)</li> <li>- игла FastCutS, совместимая с автоматическим биопсийным пистолетом FastGun®, (кат. № VES1115, VES1206, VES1207, VES12074, VES12075, VES1209, VES1210, VES1211, VES12114, VES1212, VES1213, VES1215, VES1216, VES1218, VES1220, VES1225, VES1228, VES1230, VES1407, VES14074, VES14075, VES1409, VES1410, VES1411, VES14114, VES1412, VES1413, VES1415, VES1416, VES1418, VES1420, VES1425, VES1428, VES1430, VES1607, VES16074, VES16075, VES1609, VES1610, VES1611, VES16114, VES1612, VES1613, VES1615, VES1616, VES1618, VES1620, VES1625, VES1628, VES1630, VES1807, VES18074, VES18075, VES1809, VES1810, VES1811, VES18114, VES1812, VES1813, VES1815, VES1816, VES1818, VES1820, VES1825, VES1828, VES1830, VES2007, VES20074, VES20075, VES2009, VES2010, VES2011, VES20114, VES2012, VES2013, VES2015, VES2016, VES2018, VES2020, VES2025, VES2028, VES2030, VES21075, VES2110, VES2115, VES2116)</li> <li>- игла FastCutL, совместимая с автоматическим биопсийным пистолетом FastGun® Light, (кат. № VEP1115, VEP1206, VEP1207, VEP12074, VEP12075, VEP1209, VEP1210, VEP1211, VEP12114, VEP1212, VEP1213, VEP1215, VEP1216, VEP1218, VEP1220, VEP1225, VEP1228, VEP1230, VEP1407, VEP14074, VEP14075, VEP1409, VEP1410, VEP1411, VEP14114, VEP1412, VEP1413, VEP1415, VEP1416, VEP1418, VEP1420, VEP1425, VEP1428, VEP1430, VEP1607, VEP16074, VEP16075, VEP1609, VEP1610, VEP1611, VEP16114, VEP1612, VEP1613, VEP1615, VEP1616, VEP1618, VEP1620, VEP1625, VEP1628, VEP1630, VEP1807, VEP18074, VEP18075, VEP1809, VEP1810, VEP1811, VEP18114, VEP1812, VEP1813, VEP1815, VEP1816, VEP1818, VEP1820, VEP1825, VEP1828, VEP1830, VEP2007, VEP20074, VEP20075, VEP2009, VEP2010, VEP2011, VEP20114, VEP2012, VEP2013, VEP2015, VEP2016, VEP2018, VEP2020, VEP2025, VEP2028, VEP2030, VEP21075, VEP2110, VEP2115, VEP2116)</li> </ul>



# ПРИЛОЖЕНИЕ К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ № ИМ-7.114483

Всего наименований:

5

Страница: 4

Страниц: 5

Изготовитель: **M.D.L. S.r.l., ИТАЛИЯ**

№	Номер регистрации	Наименование, нормативный документ, код:
		<p>PT13075, PT13078, PT13090, PT13094, PT13095, PT13098, PT13100, PT13104, PT13108, PT13110, PT13140, PT13144, PT13147, PT13148, PT14070, PT14074, PT14075, PT14090, PT14100, PT14110, PT14114, PT14120, PT14130, PT141500, PT14106, PT1418, PT14200, PT14250, PT14280, PT14300, PT15014, PT15034, PT15038, PT15040, PT15044, PT15048, PT15050, PT15054, PT15064, PT15070, PT15075, PT15078, PT15090, PT15094, PT15095, PT15098, PT15100, PT15104, PT15108, PT15110, PT15140, PT15144, PT15148, PT15150, PT15194, PT15198, PT15200, PT15250, PT16070, PT16074, PT16075, PT16090, PT16100, PT16110, PT16114, PT16120, PT16130, PT16150, PT16160, PT16180, PT16200, PT16250, PT16280, PT16300, PT17014, PT17034, PT17038, PT17040, PT17044, PT17048, PT1705, PT17050, PT17054, PT17064, PT17070, PT17075, PT17078, PT17090, PT17095, PT17094, PT17098, PT17100, PT17104, PT17108, PT17140, PT17144, PT17148, PT17190, PT17194, PT17198, PT17240, PT17244, PT17248, PT17250, PT18070, PT18074, PT18075, PT18090, PT18100, PT18110, PT18114, PT18120, PT18130, PT18150, PT18160, PT18180, PT18200, PT18250, PT18280, PT18300, PT19014, PT19034, PT19038, PT19040, PT19044, PT19048, PT19054, PT19064, PT19070, PT19078, PT19090, PT19094, PT19098, PT19100, PT19104, PT19108, PT19140, PT19144, PT19148, PT19198, PT20070, PT20074, PT20075, PT20090, PT20100, PT20110, PT20114, PT20120, PT20130, PT20150, PT20160, PT20180, PT20200, PT20250, PT20280, PT20300)</p> <p>- игла для аспирационной биопсии EasyLock, тип Меньжини, (кат. № PC1609, PC1610, PC1615, PC1620, PC1638, PC1685, PC1709, PC1715, PC1720, PC1807, PC1810, PC1812, PC1815, PC1820, PC1907, PC1910, PC1912, PC1915, PC1920, PC2010, PC2012, PC2015, PC2020, PC2025, PC2110, PC2112, PC2115, PC2120, PC2207, PC2210, PC2212, PC2215, PC2220)</p> <p>- игла полуавтоматическая EasyCut, тип Меньжини, (кат. № PC01607, PC01609, PC01610, PC01612, PC01615, PC01620, PC01709, PC01710, PC01712, PC01715, PC01720, PC01807, PC01809, PC01810, PC01812, PC01815, PC01820, PC01907, PC01909, PC01910, PC01912, PC01915, PC01920, PC02005, PC02007, PC02009, PC2010, PC02012, PC02015, PC02020, PC02107, PC02109, PC02110, PC02112, PC02115, PC02120, PC02207, PC02209, PC02210, PC02212, PC02215, PC02220, PC02230)</p> <p>- Набор для аспирационной биопсии по методу Меньжини EraSet (кат. № PA1509, PA1609, PA1709, PA1809, PA1909, PA2009, PA2109, PA2209)</p>
3	Мн-7.119803/7.009	<p>И-Изделия для аспирации и биопсии: устройства для аспирации и биопсии мягких тканей: 2306</p> <p>- пистолет одноразовый автоматический гильотинного типа Themy, (кат. № TY1115, TY1206, TY1207, TY12074, TY12075, TY1209, TY1210, TY1211, TY12114, TY1212, TY1213, TY1215, TY1216, TY1218, TY1220, TY1225, TY1228, TY1230, TY1407, TY14074, TY14075, TY1409, TY1410, TY1411, TY14114, TY1412, TY1413, TY1415, TY1416, TY1418, TY1420, TY1425, TY1428, TY1430, TY1607, TY16074, TY16075, TY1609, TY1610, TY1611, TY16114, TY1612, TY1613, TY1615, TY1616, TY1618, TY1620, TY1625, TY1628, TY1630, TY1807, TY18074, TY18075, TY1809, TY1810, TY1811, TY18114, TY1812, TY1813, TY1815, TY1816, TY1818, TY1820, TY1825, TY1828, TY1830, TY2007, TY20074, TY20075, TY2009, TY2010, TY2011, TY20114, TY2012, TY2013, TY2015, TY2016, TY2018, TY2020, TY2025, TY2028, TY2030, TY21075, TY2110, TY2115, TY2116)</p> <p>- Пистолет одноразовый автоматический гильотинного типа Themy Q, (кат. № TYQ1115, TYQ1206, TYQ1207, TYQ12074, TYQ12075, TYQ1209, TYQ1210, TYQ1211, TYQ12114, TYQ1212, TYQ1213, TYQ1215, TYQ1216, TYQ1218, TYQ1220, TYQ1225, TYQ1228, TYQ1230, TYQ1407, TYQ14074, TYQ14075, TYQ1409, TYQ1410, TYQ1411, TYQ14114, TYQ1412, TYQ1413, TYQ1415, TYQ1416, TYQ1418, TYQ1420, TYQ1425, TYQ1428, TYQ1430, TYQ1607, TYQ16074, TYQ16075, TYQ1609, TYQ1610, TYQ1611, TYQ16114, TYQ1612, TYQ1613, TYQ1615, TYQ1616, TYQ1618, TYQ1620, TYQ1625, TYQ1628, TYQ1630, TYQ1807, TYQ18074, TYQ18075, TYQ1809, TYQ1810, TYQ1811, TYQ18114, TYQ1812, TYQ1813, TYQ1815, TYQ1816, TYQ1818, TYQ1820, TYQ1825, TYQ1828, TYQ1830, TYQ2007, TYQ20074, TYQ20075, TYQ2009, TYQ2010, TYQ2011, TYQ20114, TYQ2012, TYQ2013, TYQ2015, TYQ2016, TYQ2018, TYQ2020, TYQ2025, TYQ2028, TYQ2030, TYQ21075, TYQ2110, TYQ2115, TYQ2116)</p>
4	Мн-7.119803/7.010	<p>И-Изделия для аспирации и биопсии: иглы для цитогистологической биопсии: 2306</p> <p>- игла CytoCut, тип Чиза, (кат. № PB1407, PB1420, PB1615, PB1620, PB1630, PB1705, PB1707, PB1710, PB1712, PB1715, PB1720, PB1725, PB1730, PB1805, PB1807, PB1810, PB1811, PB1812, PB1815, PB1818, PB1820, PB1825, PB1830, PB1835, PB1905, PB1910, PB1915, PB1920, PB1925, PB1930, PB2004, PB2005, PB2007, PB2009, PB2010, PB2011, PB2012, PB2015, PB2018, PB2020, PB2023, PB2025, PB2030, PB2105, PB2107, PB2109, PB2110, PB2112, PB2115, PB2118, PB2120, PB2125, PB2130, PB2205, PB2207, PB2209, PB2210,</p>



