



ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

№ РЗН 2014/2221

от 15 мая 2020 года

На медицинское изделие

Спирали эмболизационные для сосудистой эмболизации

Настоящее регистрационное удостоверение выдано

"Кук Медикал Юроп Лтд.", Ирландия,

Cook Medical Europe Ltd., O'Halloran Road, National Technology Park, Limerick, Ireland

Производитель

"Кук Инкорпорэйтед", США,

Cook Incorporated, 750 Daniels Way, Bloomington, IN 47404, USA

Место производства медицинского изделия

см. приложение

Номер регистрационного досье № РД-30568/83621 от 23.12.2019

Класс потенциального риска применения медицинского изделия 3

Код Общероссийского классификатора продукции по видам экономической деятельности **32.50.50.190**

Настоящее регистрационное удостоверение имеет приложение на 5 листах

приказом Росздравнадзора от 15 мая 2020 года № 3964
допущено к обращению на территории Российской Федерации.

**Заместитель руководителя Федеральной службы
по надзору в сфере здравоохранения**

Д.Ю. Павлюков

0046347

**ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ**

от 15 мая 2020 года

№ РЗН 2014/2221

Лист 1

На медицинское изделие

Спирали эмболизационные для сосудистой эмболизации:

Спирали:

DCS-11-2-2-HL-SPIRAL; DCS-11-2-4-HL-SPIRAL; DCS-11-3-4-HL-SPIRAL; DCS-11-3-6-HL-SPIRAL; DCS-11-4-10-HL-J; DCS-11-4-12-HL-SPIRAL; DCS-11-4-15-HL-J; DCS-11-4-20-HL-J; DCS-11-4-30-HL-J; DCS-11-4-5-HL-SPIRAL; DCS-11-4-8-HL-SPIRAL; DCS-11-5-10-HL-SPIRAL; DCS-11-5-15-HL-SPIRAL; DCS-11-5-6-HL-SPIRAL; DCS-11-6-12-HL-SPIRAL; DCS-11-6-15-HL-J; DCS-11-6-20-HL-J; DCS-11-6-20-HL-SPIRAL; DCS-11-6-30-HL-J; DCS-11-6-8-HL-SPIRAL; DCS-11-8-15-HL-J; DCS-11-8-30-HL-J; DCS-11-ANG-3-HL-J; DCS-11-ANG-6-HL-J; DCS-11F-2-4-HL-SPIRAL; DCS-11F-3-4-HL-SPIRAL; DCS-11F-3-6-HL-SPIRAL; DCS-11F-4-10-HL-J; DCS-11F-4-15-HL-J; DCS-11F-4-15-HL-MCJ; DCS-11F-4-20-HL-J; DCS-11F-4-20-HL-MCJ; DCS-11F-4-5-HL-SPIRAL; DCS-11F-4-8-HL-SPIRAL; DCS-11F-5-10-HL-SPIRAL; DCS-11F-5-6-HL-SPIRAL; DCS-11F-6-12-HL-SPIRAL; DCS-11F-6-15-HL-J; DCS-11F-6-15-HL-MCJ; DCS-11F-6-20-HL-J; DCS-11F-6-20-HL-MCJ; DCS-11F-6-8-HL-SPIRAL; DCS-11F-8-15-HL-J; DCS-11F-8-25-HL-J; DCS-18-10-15-HL-SPIRAL; DCS-18-10-30-HL-J; DCS-18-10-30-HL-MCJ; DCS-18-10-30-HL-SPIRAL; DCS-18-12-20-HL-SPIRAL; DCS-18-12-30-HL-J; DCS-18-12-30-HL-SPIRAL; DCS-18-12-50-HL-J; DCS-18-15-30-HL-MCJ; DCS-18-20-50-HL-J; DCS-18-4-12-HL-SPIRAL; DCS-18-4-6-HL-SPIRAL; DCS-18-6-10-HL-SPIRAL; DCS-18-6-20-HL-J; DCS-18-6-20-HL-SPIRAL; DCS-18-6-30-HL-J; DCS-18-6-30-HL-MCJ; DCS-18-8-10-HL-SPIRAL; DCS-18-8-20-HL-J; DCS-18-8-20-HL-SPIRAL; DCS-18-8-30-HL-J; DCS-18-8-30-HL-MCJ; DCS-18-8-30-HL-SPIRAL; DCS-18-8/3-14-HL-TORNADO; DCS-18S-10-20-HL-SPIRAL; DCS-18S-10-25-HL-MCJ; DCS-18S-10-30-HL-MCJ; DCS-18S-10-50-HL-J; DCS-18S-14-30-HL-SPIRAL; DCS-18S-15-50-HL-J; DCS-18S-16-50-HL-SPIRAL; DCS-18S-18-50-HL-SPIRAL; DCS-18S-20-50-HL-SPIRAL; DCS-18S-3-6-HL-SPIRAL; DCS-18S-3-9-HL-SPIRAL; DCS-18S-4-10-HL-SPIRAL; DCS-18S-4-15-HL-J; DCS-18S-4-25-HL-J; DCS-18S-4-5-HL-SPIRAL; DCS-18S-4-50-HL-J; DCS-18S-5-12-HL-SPIRAL; DCS-18S-5-7-HL-SPIRAL; DCS-18S-6-15-HL-J; DCS-18S-6-15-HL-MCJ; DCS-18S-6-15-HL-SPIRAL; DCS-18S-6-25-HL-J; DCS-18S-6-50-HL-J; DCS-18S-6-8-HL-SPIRAL; DCS-18S-8-10-HL-SPIRAL; DCS-18S-8-15-HL-J; DCS-18S-8-20-HL-MCJ; DCS-18S-8-20-HL-SPIRAL; DCS-18S-8-25-HL-J; DCS-18S-8-50-HL-J; DCS-18SF-10-15-HL-SPIRAL; DCS-18SF-10-20-HL-SPIRAL; DCS-18SF-10-25-HL-J; DCS-18SF-10-25-HL-MCJ; DCS-18SF-10-30-HL-J; DCS-18SF-10-30-HL-SPIRAL; DCS-18SF-12-30-HL-J; DCS-18SF-12-30-HL-SPIRAL; DCS-18SF-14-30-HL-SPIRAL; DCS-18SF-16-30-HL-SPIRAL; DCS-18SF-18-30-HL-SPIRAL; DCS-18SF-20-30-HL-SPIRAL; DCS-18SF-3-6-HL-SPIRAL; DCS-18SF-3-9-HL-SPIRAL; DCS-18SF-4-10-HL-SPIRAL; DCS-

**Заместитель руководителя Федеральной службы
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Д.Ю. Павлюков

0066767

**ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ**

от 15 мая 2020 года

№ РЗН 2014/2221

Лист 2

18SF-4-15-HL-J; DCS-18SF-4-25-HL-J; DCS-18SF-4-6-HL-SPIRAL; DCS-18SF-5-12-HL-SPIRAL; DCS-18SF-5-7-HL-SPIRAL; DCS-18SF-6-10-HL-SPIRAL; DCS-18SF-6-15-HL-J; DCS-18SF-6-15-HL-MCJ; DCS-18SF-6-15-HL-SPIRAL; DCS-18SF-6-25-HL-J; DCS-18SF-6-25-HL-MCJ; DCS-18SF-8-10-HL-SPIRAL; DCS-18SF-8-15-HL-J; DCS-18SF-8-15-HL-MCJ; DCS-18SF-8-20-HL-SPIRAL; DCS-18SF-8-25-HL-J; DCS-18SF-8-25-HL-MCJ; DCS-18SF-8-30-HL-SPIRAL; IMWCE-35-4-3-JACKSON; IMWCE-35-4-4-JACKSON; IMWCE-35-5-5-JACKSON; IMWCE-35-5-6-JACKSON; IMWCE-35-5-8-JACKSON; IMWCE-35-6-10-JACKSON; IMWCE-35-6-12-JACKSON; IMWCE-38-4-3-JACKSON; IMWCE-38-4-4-JACKSON; IMWCE-38-5-5-JACKSON; IMWCE-38-5-6-JACKSON; IMWCE-38-5-8-JACKSON; IMWCE-38-6-10-JACKSON; IMWCE-38-6-12-JACKSON; IMWCE-3-PDA3; IMWCE-3-PDA4; IMWCE-3-PDA5; IMWCE-5-PDA3; IMWCE-5-PDA4; IMWCE-5-PDA5; IMWCE-6.5-PDA3; IMWCE-6.5-PDA4; IMWCE-6.5-PDA5; IMWCE-8-PDA3; IMWCE-8-PDA4; IMWCE-8-PDA5; MWCE-18S-1.2-2-A; MWCE-18S-1.8-3-A; MWCE-18S-2.0-5-B; MWCE-18S-2.4-4-A; MWCE-18S-2.6-3-C; MWCE-18S-3.0-7-B; MWCE-18S-3.5-4-C; MWCE-18S-4.2-10-B; MWCE-18S-5.2-12-B; MWCE-18S-0.5-0-HILAL; MWCE-18S-0.7-0-HILAL; MWCE-18S-1.0-0-HILAL; MWCE-18S-1.0-3-HILAL; MWCE-18S-1.5-0-HILAL; MWCE-18S-1.5-5-HILAL; MWCE-18S-2.0-2-HILAL; MWCE-18S-2.0-4-HILAL; MWCE-18S-2.1-7-HILAL; MWCE-18S-3.0-10-HILAL; MWCE-18S-3.0-3-HILAL; MWCE-18S-3.0-4-HILAL; MWCE-18S-4.0-6-HILAL; MWCE-18S-4.0-7-HILAL; MWCE-18S-6.0-5-HILAL; MWCE-18S-6.0-7-HILAL; IMWCE-25-1.2-2; IMWCE-25-2.5-2; IMWCE-25-2-2; IMWCE-25-2-3; IMWCE-25-3-2; IMWCE-25-3-3; IMWCE-25-3-5; IMWCE-25-4-3; IMWCE-25-5-5; IMWCE-25-5-8; IMWCE-35-1.5-3; IMWCE-35-1.5-5; IMWCE-35-10-10; IMWCE-35-10-12; IMWCE-35-10-15; IMWCE-35-10-20; IMWCE-35-10-4; IMWCE-35-10-5; IMWCE-35-10-6; IMWCE-35-10-8; IMWCE-35-1-2; IMWCE-35-12-10; IMWCE-35-12-5; IMWCE-35-12-8; IMWCE-35-1-3; IMWCE-35-14-12; IMWCE-35-14-3; IMWCE-35-14-5; IMWCE-35-14-6; IMWCE-35-14-8; IMWCE-35-1-5; IMWCE-35-15-10; IMWCE-35-15-12; IMWCE-35-15-15; IMWCE-35-15-20; IMWCE-35-15-5; IMWCE-35-2.5-5; IMWCE-35-20-10; IMWCE-35-20-15; IMWCE-35-20-20; IMWCE-35-2-2; IMWCE-35-2-3; IMWCE-35-2-4; IMWCE-35-2-5; IMWCE-35-2-8; IMWCE-35-3-10; IMWCE-35-3-2; IMWCE-35-3-3; IMWCE-35-3-4; IMWCE-35-3-5; IMWCE-35-3-6; IMWCE-35-3-7; IMWCE-35-3-8; IMWCE-35-4-2; IMWCE-35-4-3; IMWCE-35-4-4; IMWCE-35-4-5; IMWCE-35-4-6; IMWCE-35-4-7; IMWCE-35-4-8; IMWCE-35-5-10; IMWCE-35-5-12; IMWCE-35-5-15; IMWCE-35-5-2; IMWCE-35-5-3; IMWCE-35-5-4; IMWCE-35-5-5; IMWCE-35-5-6; IMWCE-35-5-7; IMWCE-35-5-8; IMWCE-35-6-10; IMWCE-35-6-3; IMWCE-35-6-4; IMWCE-35-6-5; IMWCE-35-6-6; IMWCE-35-6-7; IMWCE-35-6-8; IMWCE-35-7-3; IMWCE-35-7-5;

**Заместитель руководителя Федеральной службы
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Д.Ю. Павлюков

0066768

**ПРИЛОЖЕНИЕ
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Лист 3

IMWCE-35-8-10; IMWCE-35-8-12; IMWCE-35-8-15; IMWCE-35-8-4; IMWCE-35-8-5;
IMWCE-35-8-6; IMWCE-35-8-8; IMWCE-38-1.5-3; IMWCE-38-1.5-5; IMWCE-38-10-10;
IMWCE-38-10-12; IMWCE-38-10-15; IMWCE-38-10-20; IMWCE-38-10-5; IMWCE-38-
10-6; IMWCE-38-10-7; IMWCE-38-10-8; IMWCE-38-1-2; IMWCE-38-12-10; IMWCE-38-
12-12; IMWCE-38-12-14; IMWCE-38-12-5; IMWCE-38-12-8; IMWCE-38-1-3; IMWCE-
38-13-8; IMWCE-38-15-10; IMWCE-38-15-12; IMWCE-38-15-15; IMWCE-38-15-2;
IMWCE-38-15-20; IMWCE-38-15-25; IMWCE-38-15-30; IMWCE-38-15-8; IMWCE-38-
16-45; IMWCE-38-2.5-5; IMWCE-38-20-15; IMWCE-38-2-2; IMWCE-38-2-3; IMWCE-38-
2-4; IMWCE-38-2-5; IMWCE-38-2-6; IMWCE-38-2-8; IMWCE-38-3-2; IMWCE-38-3-3;
IMWCE-38-3-4; IMWCE-38-3-5; IMWCE-38-3-7; IMWCE-38-3-8; IMWCE-38-4-10;
IMWCE-38-4-12; IMWCE-38-4-3; IMWCE-38-4-4; IMWCE-38-4-5; IMWCE-38-4-6;
IMWCE-38-4-7; IMWCE-38-4-8; IMWCE-38-5-10; IMWCE-38-5-12; IMWCE-38-5-15;
IMWCE-38-5-2; IMWCE-38-5-20; IMWCE-38-5-3; IMWCE-38-5-4; IMWCE-38-5-5;
IMWCE-38-5-6; IMWCE-38-5-7; IMWCE-38-5-8; IMWCE-38-5-9; IMWCE-38-6-10;
IMWCE-38-6-12; IMWCE-38-6-15; IMWCE-38-6-3; IMWCE-38-6-4; IMWCE-38-6-5;
IMWCE-38-6-6; IMWCE-38-6-8; IMWCE-38-7-5; IMWCE-38-8-10; IMWCE-38-8-12;
IMWCE-38-8-15; IMWCE-38-8-3; IMWCE-38-8-4; IMWCE-38-8-5; IMWCE-38-8-6;
IMWCE-38-8-8; IMWCE-38-9-5; MWCE-18-0.5-0-HILAL; MWCE-18-0.7-0-HILAL;
MWCE-18-1.0-0-HILAL; MWCE-18-1.0-2-HILAL; MWCE-18-1.0-3-HILAL; MWCE-18-
1.5-0-HILAL; MWCE-18-1.5-5-HILAL; MWCE-18-2.0-2-HILAL; MWCE-18-2.0-3-
HILAL; MWCE-18-2.0-4-HILAL; MWCE-18-2.1-7-HILAL; MWCE-18-3.0-10-HILAL;
MWCE-18-3.0-3-HILAL; MWCE-18-3.0-4-HILAL; MWCE-18-4.0-6-HILAL; MWCE-18-
4.0-7-HILAL; MWCE-18-6.0-10-HILAL; MWCE-18-6.0-5-HILAL; MWCE-18-6.0-7-
HILAL; MWCE-18-14-10-NESTER; MWCE-18-14-3-NESTER; MWCE-18-14-4-NESTER;
MWCE-18-14-6-NESTER; MWCE-18-14-8-NESTER; MWCE-18-3-2-NESTER; MWCE-
18-3-3-NESTER; MWCE-18-4-3-NESTER; MWCE-18-5-2-NESTER; MWCE-18-5-3-
NESTER; MWCE-18-7-10-NESTER; MWCE-18-7-2-NESTER; MWCE-18-7-3-NESTER;
MWCE-18-7-4-NESTER; MWCE-18-7-6-NESTER; MWCE-18-7-8-NESTER; MWCE-35-
14-10-NESTER; MWCE-35-14-12-NESTER; MWCE-35-14-14-NESTER; MWCE-35-14-
16-NESTER; MWCE-35-14-18-NESTER; MWCE-35-14-20-NESTER; MWCE-35-14-4-
NESTER; MWCE-35-14-6-NESTER; MWCE-35-14-8-NESTER; MWCE-35-20-18-
NESTER; MWCE-35-20-20-NESTER; MWCE-35-4-4-NESTER; MWCE-35-4-5-NESTER;
MWCE-35-6-6-NESTER; MWCE-35-7-10-NESTER; MWCE-35-7-12-NESTER; MWCE-
35-7-14-NESTER; MWCE-35-7-16-NESTER; MWCE-35-7-18-NESTER; MWCE-35-7-20-
NESTER; MWCE-35-7-4-NESTER; MWCE-35-7-6-NESTER; MWCE-35-7-8-NESTER;
MWCE-35-8-8-NESTER; MWCE-38-14-10-NESTER; MWCE-38-14-12-NESTER;

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**ПРИЛОЖЕНИЕ
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НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ**

от 15 мая 2020 года

№ РЗН 2014/2221

Лист 4

MWCE-38-14-14-NESTER; MWCE-38-14-16-NESTER; MWCE-38-14-18-NESTER;
MWCE-38-14-20-NESTER; MWCE-38-14-4-NESTER; MWCE-38-14-6-NESTER;
MWCE-38-14-8-NESTER; MWCE-38-20-18-NESTER; MWCE-38-20-20-NESTER;
MWCE-38-4-4-NESTER; MWCE-38-4-6-NESTER; MWCE-38-6-6-NESTER; MWCE-38-
7-10-NESTER; MWCE-38-7-12-NESTER; MWCE-38-7-14-NESTER; MWCE-38-7-16-
NESTER; MWCE-38-7-18-NESTER; MWCE-38-7-20-NESTER; MWCE-38-7-4-NESTER;
MWCE-38-7-6-NESTER; MWCE-38-7-8-NESTER; MWCE-38-8-8-NESTER; MWCE-18S-
10/4-TORNADO; MWCE-18S-10/5-TORNADO; MWCE-18S-2/3-TORNADO-LEF;
MWCE-18S-2/4-TORNADO-LEF; MWCE-18S-2/5-TORNADO-LEF; MWCE-18S-2/6-
TORNADO-LEF; MWCE-18S-2/7-TORNADO-LEF; MWCE-18S-3/2-TORNADO;
MWCE-18S-3/7-TORNADO-LEF; MWCE-18S-4/10-TORNADO-LEF; MWCE-18S-4/2-
TORNADO; MWCE-18S-4/3-TORNADO; MWCE-18S-4/8-TORNADO-LEF; MWCE-18S-
5/10-TORNADO-LEF; MWCE-18S-5/2-TORNADO; MWCE-18S-5/8-TORNADO-LEF;
MWCE-18S-6/2-TORNADO; MWCE-18S-7/2-TORNADO; MWCE-18S-7/3-TORNADO;
MWCE-18S-8/4-TORNADO; MWCE-18S-8/5-TORNADO; MWCE-35-10/3-TORNADO;
MWCE-35-10/4-TORNADO; MWCE-35-10/5-TORNADO; MWCE-35-3/10-TORNADO-
LEF; MWCE-35-3/4-TORNADO-LEF; MWCE-35-3/4-TORNADO-LEF-HIRATA-061499;
MWCE-35-3/5-TORNADO-LEF; MWCE-35-3/5-TORNADO-LEF-HIRATA-061499;
MWCE-35-3/6-TORNADO-LEF; MWCE-35-3/6-TORNADO-LEF-HIRATA-061499;
MWCE-35-3/7-TORNADO-LEF; MWCE-35-3/7-TORNADO-LEF-HIRATA-061499;
MWCE-35-4/10-TORNADO-LEF; MWCE-35-4/3-TORNADO; MWCE-35-4/8-
TORNADO-LEF; MWCE-35-4/8-TORNADO-LEF-HIRATA-061499; MWCE-35-5/10-
TORNADO-LEF; MWCE-35-5/10-TORNADO-LEF-HIRATA-061499; MWCE-35-5/3-
TORNADO; MWCE-35-5/8-TORNADO-LEF; MWCE-35-6/3-TORNADO; MWCE-35-7/3-
TORNADO; MWCE-35-8/4-TORNADO; MWCE-35-8/5-TORNADO; MWCE-38-10/3-
TORNADO; MWCE-38-10/4-TORNADO; MWCE-38-10/5-TORNADO; MWCE-38-3/6-
TORNADO-LEF; MWCE-38-4/3-TORNADO; MWCE-38-4/8-TORNADO-LEF; MWCE-
38-5/10-TORNADO-LEF; MWCE-38-5/3-TORNADO; MWCE-38-6/3-TORNADO;
MWCE-38-7/3-TORNADO; MWCE-38-8/4-TORNADO; MWCE-38-8/5-TORNADO;
MWCE-25-1.2-2; MWCE-25-2.5-2; MWCE-25-2-3; MWCE-25-2-5; MWCE-25-3-2;
MWCE-25-3-3; MWCE-25-3-4; MWCE-25-3-5; MWCE-25-4-3; MWCE-25-5-5; MWCE-
35-1.2-2; MWCE-35-1.5-2; MWCE-35-10-10; MWCE-35-10-12; MWCE-35-10-15;
MWCE-35-10-4; MWCE-35-10-5; MWCE-35-10-8; MWCE-35-1-2; MWCE-35-12-10;
MWCE-35-12-5; MWCE-35-1-3; MWCE-35-14-12; MWCE-35-14-5; MWCE-35-14-6;
MWCE-35-14-8; MWCE-35-15-10; MWCE-35-15-12; MWCE-35-15-15; MWCE-35-15-20;
MWCE-35-2.5-2; MWCE-35-2-2; MWCE-35-2-3; MWCE-35-2-4; MWCE-35-2-5; MWCE-

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НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ**

от 15 мая 2020 года

№ РЗН 2014/2221

Лист 5

35-2-8; MWCE-35-3-10; MWCE-35-3-2; MWCE-35-3-3; MWCE-35-3-4; MWCE-35-3-5;
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35-4-4; MWCE-35-4-5; MWCE-35-4-6; MWCE-35-4-7; MWCE-35-4-8; MWCE-35-5-10;
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35-6-3; MWCE-35-6-4; MWCE-35-6-5; MWCE-35-6-6; MWCE-35-7-3; MWCE-35-7-5;
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16; MWCE-35-7-18; MWCE-35-7-20; MWCE-35-7-4; MWCE-35-7-6;
MWCE-35-7-8.

Место производства:

1. Cook Incorporated, 750 Daniels Way, Bloomington, IN 47404, USA.
2. William Cook Europe ApS, Sandet 6, 4632 Bjaeverskov, Denmark.

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по надзору в сфере здравоохранения

Д.Ю. Павлюков

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