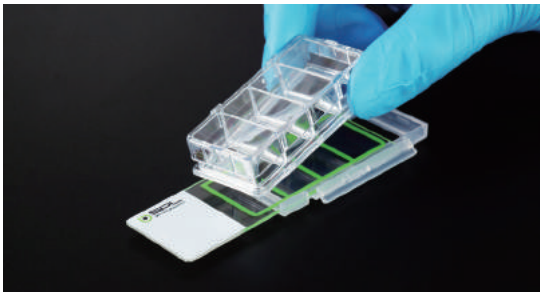
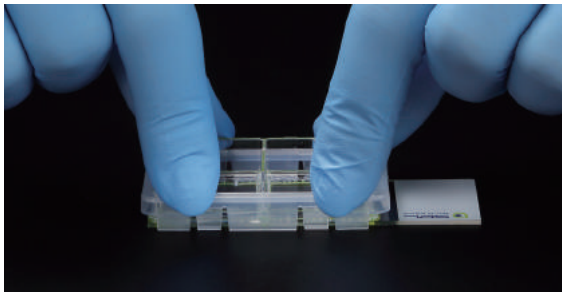
Cell Culture Slide I, II / Hybridwell™



Cell Culture Slide I: Lean back both sides tabs and then chamber and holder will be removed from slide.

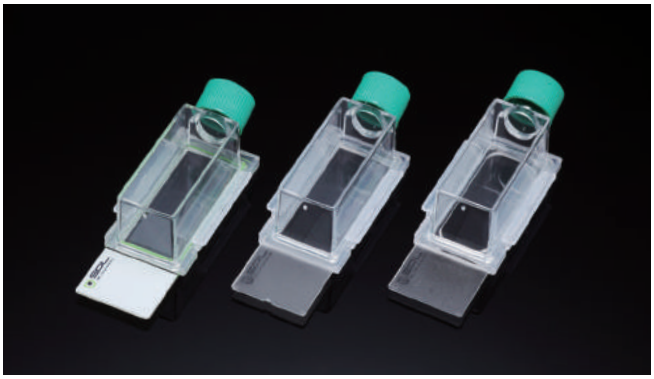


Cell Culture Slide II: Press chamber from top to bottom, then lean back and remove holder and chamber.

Cell Culture Slide Hybridwell™ is a combination of conventional cell culture flask and single well slide, providing better and safer handling of samples.

- Convenient for microscopic observation
- Bottom materials: Glass / DLux / FLux (no surface treatment for glass bottom)
- Chamber color: Clear
- Easy open flip for chamber & slide disassembly
- No chemical adhesives used
- Packing trays can be used as incubation racks in CO_2 incubators

- Non–pyrogenic
- Non–cytotoxic
- DNase / RNase-free
- Human DNA-free



Cell Culture Slide Hybridwell™

Type	Cat. No.	Material (Chamber / Slide / Holder)	Chamber Color	Growth Area (cm^2)	Working Vol. (ml)	Surface Treatment	Sterile	Packaging
	33101	PS / Glass / PP	Clear	9.00	2.50 - 5.50	-	+	6 / 12
	33201	PS / DLux / PP	Clear	9.00	2.50 - 5.50	+	+	6 / 12
	33301	PS / FLux / PP	Clear	9.00	2.50 - 5.50	+	+	6

Certificate of Registration

In accordance with European Communities Council Directive 98/79/EC as amended, concerning In Vitro Medical Devices as transposed into European national law by the member states

Certificate No.
KOR/2015/07/01

Certificate issue date;
9th October 2018

Certificate expiry date;
31st October 2019

We hereby declare that

- **An examination has been made of this organisation's Declaration of Conformity(s) and where appropriate Notified Body certification(s) exist.**
- **The EU Authorised Representative contract has been fulfilled**

And the CE mark may be applied to the products listed below.

Organisation / Client:

SPL Life Sciences Co., Ltd
26 Geumgang-ro 2047 beon-gil
Naechon-Myeon, Pocheon-si
Gyeonggi-do 487 835
Republic of Korea

Products:

Cell Strainer, Cell Culture Plate, Cell Culture Dish, Cell Culture Slide & Cell Culture Flask

Competent Authority Information:

IVD Medical Device Directive registration is with the UK Medicines and Healthcare Regulatory Agency (MHRA) and the below registration has been issued.

IVD000839

Authorised Representative Labelling Information:

EC REP Advena Ltd. Pure Offices, Plato Close, Warwick CV34 6WE UK.

Advena Limited.

Registered office;
Pure Offices, Plato Close, Tachbrook Park
Warwick CV34 6WE. United Kingdom
Registered in England & Wales No. 3517275

☎ +44 1926 800153
Email; info@advenamedical.com

Authorised Signature:

This certificate is subject to the organisation maintaining their documentation in compliance with the regulations stated in this certificate.

This certificate is for the exclusive use of Advena Ltd's client and is provided pursuant of the European Authorised Representative agreement (Mandate) between Advena Ltd and the client. Advena's responsibility and liability is limited to the terms and conditions of this agreement. Advena Ltd assumes no liability to any party for any loss, expense or damage occasioned by the use of this certificate and the European Authorised Representative agreement (Mandate). Only the client is authorised to copy or distribute this certificate. Any use of the Advena Ltd name by others who are not covered by the above agreement, or any similar contract, is prohibited. This certificate remains valid until the expiry date has been reached or has been terminated by Advena Limited.

Declaration of Conformity

Manufacturer:	**SPL Life Sciences, Co., Ltd** 26, Geumgnag-ro 2047 beon-gil, Naechon-myeon, Pocheon-si, Gyeonggi-do, 487-835, Korea
European Representative:	Advena Ltd, Pure Offices, Plato Close, Tachbrook Park, Warwick, Warwickshire, CV34 6WE, UK
Product:	Cell Culture Slide (1/2/4/8well/Hybridwell) Cat. No. 30101/30111/30121/30401/30501 30102/30112/30122/30402/30502 30104/30114/30124/30404/30504 30108/30118/30128/30408/30508 33101/33201/33301
Classification:	*In vitro* diagnostic medical devices according to Annex III of Directive 98/79/EC (neither listed in Annex II, nor intended for self testing)
Conformity Assessment Route:	Annex III of Directive 98/79/EC

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC on *in vitro* diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standard Applied:	EN ISO 13485:2012 (Certificate No.: M-0369/15) ISO 9001:2008 (Ceretificate No.: KQA-Q031478)
Signature: 이 정상 2017. 11. 15.	Jeongsang Yi/ R&D Director SPL Life Science, Co., Ltd.

KQA
Q.Assurance

KAB-QC-05

Certificate of Approval

Accredited by Member of the International Accreditation Forum Multilateral Recognition Arrangement for Quality Management systems

KQA approves that the Quality Management System of the following company is conformed with the certification audit criteria.

Certificate No. : KQA-Q031478

Company : **SPL LIFE SCIENCES CO., LTD.**

Address : 26, Geumgang-ro 2047beon-gil, Naechon-myeon, Pocheon-si, Gyeonggi-do, Republic of Korea

The standards for this certificate of conformity are as follows.

Management Systems Standards :

ISO 9001:2015 / KS Q ISO 9001:2015

Scope of Registration :

Manufacture of Plastic injection molding

Original Approval : 8 September 2003

Validity : 6 May 2018 ~ 5 May 2021

Date of issue : 16 April 2018

(Renewal of certificate and Standard revision)

Park Jong Baik
Lead Auditor

Song Jong Cheol
CEO

Korea Quality Assurance

Korea Quality Assurance(KQA) is accredited by Korea Accreditation Board(KAB) as ISO 9000 Certification Body/Register. (Accreditation No. : KAB-QC-05)

KQA Address : 2Fl., Hojeong Bldg., 49, Manan-ro, Manan-gu, Anyang-si, Gyeonggi-do, 14034, Republic of Korea

SNAS
Reg. No. 305/Q-054

CERTIFICATE

This certifies that the Quality management system for medical devices of company

SPL Life Sciences

26, Geumkang-ro 2047beon-gill, Naechon-myeon, Pocheon-city, Gyeonggi-do, 11192, Korea

has been assessed by 3EC International and found to be in conformance with the following standard:

EN ISO 13485:2016

for the following scope:

DESIGN, DEVELOPMENT, MANUFACTURE AND SALES OF NON ACTIVE MEDICAL DEVICES AND IN VITRO DIAGNOSTIC MEDICAL DEVICES;

IVF PRODUCTS, CELL CULTURE SLIDE, CELL CULTURE PLATE, CELL CULTURE DISH, CELL CULTURE FLASK, CELL STRAINER, CONICAL TUBE, SNAP TUBE, CRYOVIAL, SEROLOGICAL PIPETTE, CYTO PAP BRUSH, MEDIA BOTTLE, ROLLER BOTTLE

Certificate No.: M-0369/18 **Date of issuance: September 28th, 2018** **Original date of approval: October 7th, 2015**

This certificate is valid from **October 6th, 2018** to **October 5th, 2021** on condition that organization will maintain effective quality management system. To verify the validity of this certificate please contact our office at: +421 (0)2 5831 8343.

Issuing office: 3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic

Dr. Katarína Tomin Srdošová
Head of Certification Body 3EC International a.s.

Certification body 3EC International a.s. is accredited by SNAS under registration number 305/Q-054 with the accreditation certificate No. Q-054 for certification of Quality management systems for medical devices.

SPL Life Sciences Co., Ltd
26, Geumgang-ro 2047 beon-gil, Naechon-Myeon,
Pocheon-si, Gyeonggi-do 487-835, Korea
Tel. +82-31-533-4800 Fax. +82-31-533-1430
www.spllifesciences.com

SPL LIFESCIENCES

Certificate of Compliance

Product Description	:	**Cell culture slide, Hybridwell Chamber/Slide/Holder(PS/Dlux/PP)**
Catalog Number	:	33201
Lot Number	:	BA8E28A33201
Expiry Date	:	05/2021 (3years from date of sterilization)

Visual Attribute	:	*PASS*
Functional Test	:	*PASS*
Sterilization	:	We hereby certify that the goods specified above have been duly sterilized by Ethylene-Oxide gas, ISO 11135-1 standard. The expiry date of sterilization by E.O. gas is normally about 3 years from the date of sterilization. The expiry date is changeable depend on user's laboratory environments.
Cytotoxicity Test	:	Cytotoxicity test is conducted to qualify all material resins using USP class VI<87> and/or ISO 10993 standards for cytotoxicity and have been shown to be non-toxic
Pyrogens Test	:	Non-pyrogenic tested according to the principles of the LAL test described in USP<85>/ 0.5EU/ml

✓ SPL Lifesciences Co., Ltd. hereby certifies that the product identified above have been inspected in compliance with product quality specification and requirements as documented in our ISO 9001:2015 Quality Management System (K-QA-Q031478) in Korea

Date :06. 11. 2018.

Authorized Signature : **S. Y. Kim**

Quality Control / Manager

For further technical information, please visit : www. spllifescience.com