

# SUN PROTECTION FIELD - SUBSTRATE

*Compliance control of substrate following  
ISO 24443:2012 – FDA monograph 2011 – Boots Star Rating System 2011*

**SUNCERT**

---

43 rue Condorcet  
60700 PONT-SAINT-MAXENCE  
France  
Email: [contact@suncert.fr](mailto:contact@suncert.fr)  
Website: [www.suncert.fr](http://www.suncert.fr)

---

## Agenda

Summary	1
Steps	2
General control	3
Technical control	4
Conclusion	Erreur ! Signet non défini.

## Summary

Beyond the certification of the competence of laboratories assessment of sun protection, it is important to have confidence in the conformity of equipment, consumables and services provided by suppliers with standards and methods.

For this, each product (equipment and consumable) and service (calibration and interlaboratory campaign) shall meet a complete technical specification extracted from the standards and methods.

In addition, each batch/serial certificate of these products/services should be also checked to ensure sustainability of compliance.

SUBSTRATE	
<b>Type:</b>	Sun protection field - Substrate
<b>Goal(s) and scope(s):</b>	Check the quality and technical specifications of substrate to comply with in vitro sunscreen testing methods
<b>Reference(s):</b>	ISO 24443:2012 FDA monograph 2011 Boots Star Rating System 2011

DOCUMENT	
<b>Reference:</b>	PARTNER-SUBSTRATE-V1
<b>Creation date:</b>	24/02/17
<b>Revision date:</b>	14/02/18
<b>Content:</b>	1. General control 2. Technical control
<b>Status:</b>	Applicable
<b>Editor(s):</b>	Sébastien MIKSA (SUNCERT)

## Steps

---

### General control

To ensure a minimum quality level, the inspected company should have a quality system management.

At least one Certification / Label is required.

Note: If none is available, a complementary audit should be necessary including management system, subcontracting services, control of records in general and technical, internal audits, management reviews, equipment, accommodation and environment, confidentiality, etc.

### Technical control

The second part concerns the technical characteristics inspection of the substrate dedicated to the sun protection field.

For the technical part, the control results, used protocols and associated certificates (if applicable) are required to be valid.

## General control

Subject	Yes	No	NA /NE	Comment
<b>1. GENERAL</b>				
1.1. <i>Certification / Label</i>				
➤ ISO 9001				
➤ ISO 13485				
➤ ISO 17025				
➤ ISO 17043				
➤ FDA registred				
➤ GMP (Good Manufacturing Practice)				
➤ GLP (Good Laboratory Practice)				
➤ GCP (Good Clinical Practice)				

## Technical control

Subject	Limit	Yes	No	NA /NE	Comment
<b>2. SUBSTRATE</b>					
<b>2.1. General</b>					
➤ Material	<b>ISO 24443:2012</b> PMMA molded <b>FDA monograph 2011</b> PMMA molded or PMMA sandblasted <b>Boots Star Rating System 2011</b> PMMA or Quartz or other material with similar and reliable results				
➤ Application area	<b>ISO 24443:2012</b> $\geq 16 \text{ cm}^2$ <b>FDA monograph 2011</b> $\geq 16 \text{ cm}^2$ <b>Boots Star Rating System 2011</b> $\geq 20 \text{ cm}^2$				
➤ Size	<b>FDA monograph 2011</b> Sides $\geq 4 \text{ cm}$				
➤ Surface	No surface energy treatment (physical and/or chemical) and without any traces of suction cup, finger, silicone, dust, black or white points, injection core, scratch, etc.				
➤ Characteristics	UV-transparent, non-fluorescent, photo-stable, inert towards all ingredients of the preparations to be tested and temperature operational range at least between 20-40°C				
<b>2.2. Technical</b>					
➤ Topographic parameters values	<b>ISO 24443:2012</b> [Ra ( $\mu\text{m}$ ): $4.85 \pm 0.32$ ]; [Rv ( $\mu\text{m}$ ): $13.04 \pm 0.63$ ]; [Rdq ( $^\circ$ ): $11.12 \pm 1.29$ ]; [A1 ( $\mu\text{m}^2/\text{mm}$ ): $239.75 \pm 44.51$ ]; [Ssc (L/ $\mu\text{m}$ ): $0.03 \pm 0.01$ ]; [Vvv (mL/m <sup>2</sup> ): $1.04\text{E}-6 \pm 6.19\text{E}-7$ ] <b>FDA monograph 2011</b> [Sa ( $\mu\text{m}$ ): 2 - 7] <b>Boots Star Rating System 2011</b> [Sa ( $\mu\text{m}$ ): 2 - 6]				
➤ Transmittance specifications	<b>ISO 24443:2012</b> Transmission values using a treated plate with glycerin against blank air [290 nm: >60 %T]; [300 nm: >69 %T]; [320 nm: >81 %T]				
<b>2.3. Control</b>					
➤ Certificate	Per batch, a quality certificate including (i) the measured results of each topographic parameters and transmittance specifications, (ii) the control date of raw material, visual characteristics and roughness				
➤ Topographic parameters control	<b>ISO 24443:2012</b> Surface area of 10 mm x 5 mm in 15- $\mu\text{m}$ intervals using a non-contact sensor with light chromatic aberration principle and high resolution (10 nm in z and 1 $\mu\text{m}$ in x and y) <b>FDA monograph 2011</b> Surface area parameters measurement following an ad hoc international standard <b>Boots Star Rating System 2011</b> Area surface parameters measurement following standard EUR 15178 EN				