



Ministero della Salute



AIFA

Agenzia Italiana del Farmaco

Bollino

*The Italian Security Label
for
Pharmaceutical Products*

The Italian Security label for Pharmaceutical products (Bollino) is a two-layer paper label:

- The lower layer shows the unique serial number (UID). It will remain attached to the pack for the entire period of validity of the pharmaceutical product and in case of attempts of removal it acts as anti-tampering device;
- The upper layer shows the following information:
 - The AIC code in both clear and code 39 barcode form;
 - The company that holds the AIC in the Italian regulation system;
 - The name of the medicine with pharmaceutical form, dosage indication and number of dose units;
 - The unique serial number (UID) in both clear and barcode form.



AIC

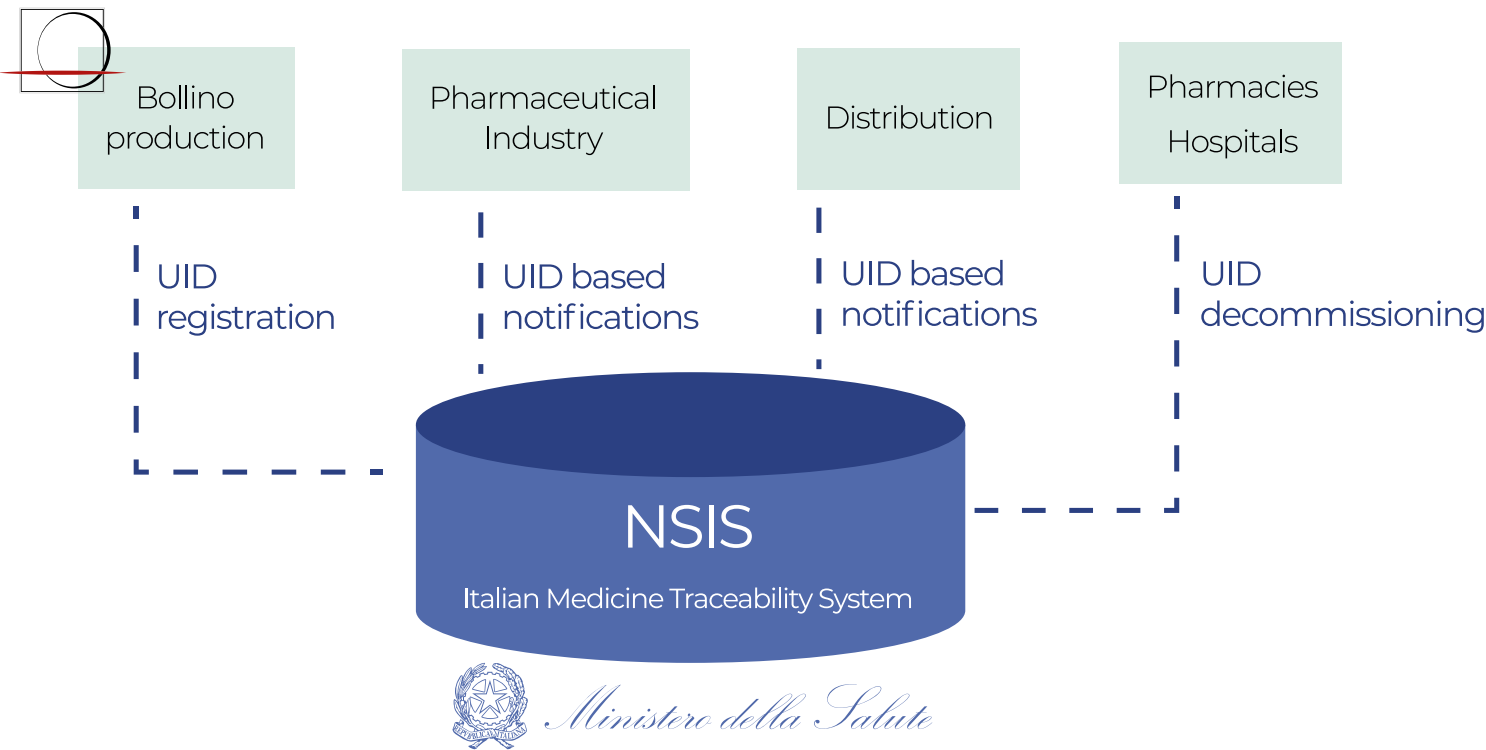
UID

NSIS

Is the medecine marketing authorization code issued by A.I.F.A. (Agenzia Italiana del Farmaco) the Italian National Authority responsible for human drugs regulation.

The unique serial number is issued by Poligrafico e Zecca dello Stato, the Italian National Printing House, and represents both the traceability unique identifier and the unique reimbursement code.

Is the National Traceability System owned and managed by the Ministry of Health.



Upper layer:

- Size: 35 mm X 25 mm;
- Watermarked paper with rhombus shape;
- UV dull paper treatment;
- Security fibers in light blue and yellow colours



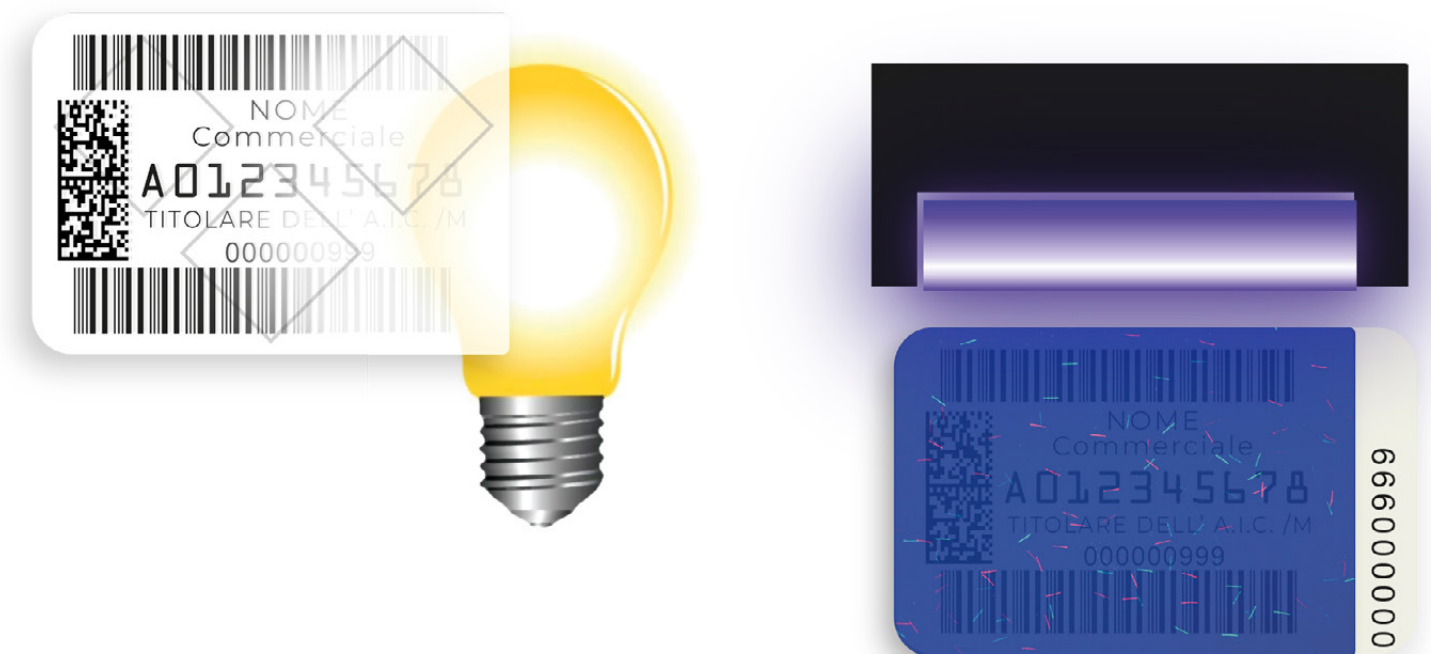
Lower layer:

- Size: 40 mm X 25 mm;
- Printed text "SICUREZZA" and symbol of the caduceus, red ink



Security checks

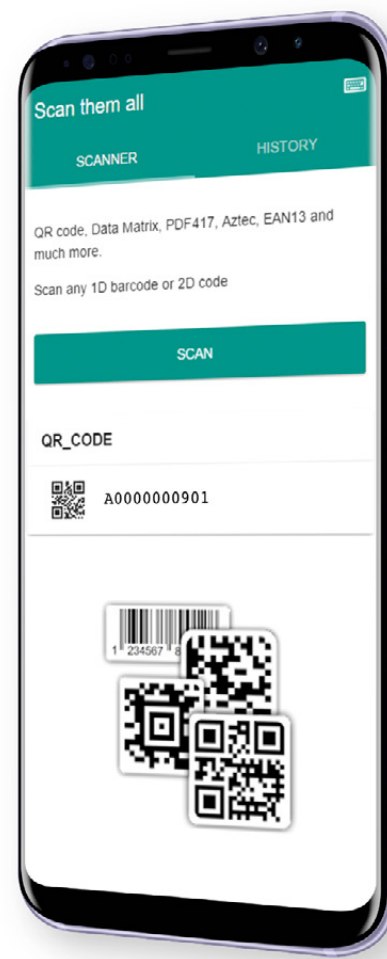
1. UV lamp exposal:
 - a. Security fibers reaction to UV light
 - b. Paper surface reaction to UV light (UV Dull security element)
2. Watermark shapes visible when the upper layer is held against the light



Barcode check with smartphone's app:

Using a general purpose code scanner app for smartphone (e.g. Scan them all) scan the barcodes and check:

- 1 The AIC number in code 39 form
- 2 The UID (correspondent to the two clear versions printed on the lower and the upper layer)
- 3 The combination of the UID and AIC number in code 39 form



On behalf of the Italian Authorities, Poligrafico supplies Bollino with the following responsibilities:

- production under the GMP and ISO standards, including ISO-14298 Intergraph for security printing (Governmental Level);
- 100% quality control on the total amount of Bollino produced;
- collaboration with all the national control bodies to support investigations;
- sworn and certified testimony of authenticity required by the investigation authorities.

Any further check on UID validity and Bollino's physical authenticity can be requested to the Italian authorities



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The Italian Ministry of Health with AIFA and the technical support of Poligrafico
are evaluating further innovative solutions for coding and labeling
against counterfeiting and frauds
(e.g. for a stronger control of parallel trade)

