



*Giunta Regionale della Campania
Direzione Generale per la Tutela della Salute ed il
Coordinamento del Sistema Sanitario Regionale*

*Ai Direttori Generali AA.SS.LL.
Ai Direttori Dip./Serv. Farmaceutici*

e, per il Loro tramite

*Ai Titolari dei Distributori Ingrosso di farmaci di competenza
territoriale*

Al Presidente Federfarma Campania

e, per il Suo tramite

*Ai Presidenti di Federfarma Av Bn Ce Na Sa
Ai Titolari e Direttori di farmacia privata
Al Coordinatore Regionale Assofarm*

e, per il Suo tramite

*Ai Direttori farmacia pubblica
A ADF
Agli Ordini Professionali dei Farmacisti*

e, p.c.

Al Comando Carabinieri del NAS CE, NA, SA

REGIONE CAMPANIA

Prot. 2019. 0097248 12/02/2019 13,31

Mitt. : 500406 Politica del farmaco e disposi...

Dest. : AI DIRETTORI GENERALI AA.SS.LL. REGIONE CAMPANIA

Classifica : 50.4. Fascicolo : 27 del 2019



Oggetto: Documento 'Bollino' elaborato dal Poligrafico e Zecca dello Stato Italiano

Alla luce degli ultimi avvenimenti di cronaca e della diffusione di farmaci provvisti di "fustelli ottici contraffatti", si trasmette in allegato alla presente il documento elaborato dal Poligrafico e Zecca dello Stato Italiano in collaborazione con il Ministero della Salute e l'AIFA invitando, al contempo, gli enti in indirizzo a darne debita comunicazione in modo da aumentare il dovuto livello di attenzione.

Contando sulla collaborazione si porgono cordiali saluti.

Il Dirigente UOD 06
Dott. Ugo TRAMA



Ministero della Salute

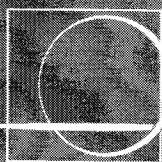


AIFA

Agenzia Italiana del Farmaco

Bollino

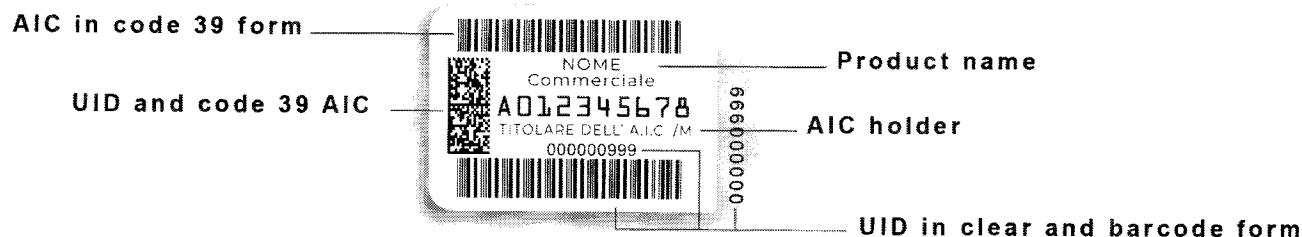
*The Italian Security Label
for
Pharmaceutical Products*



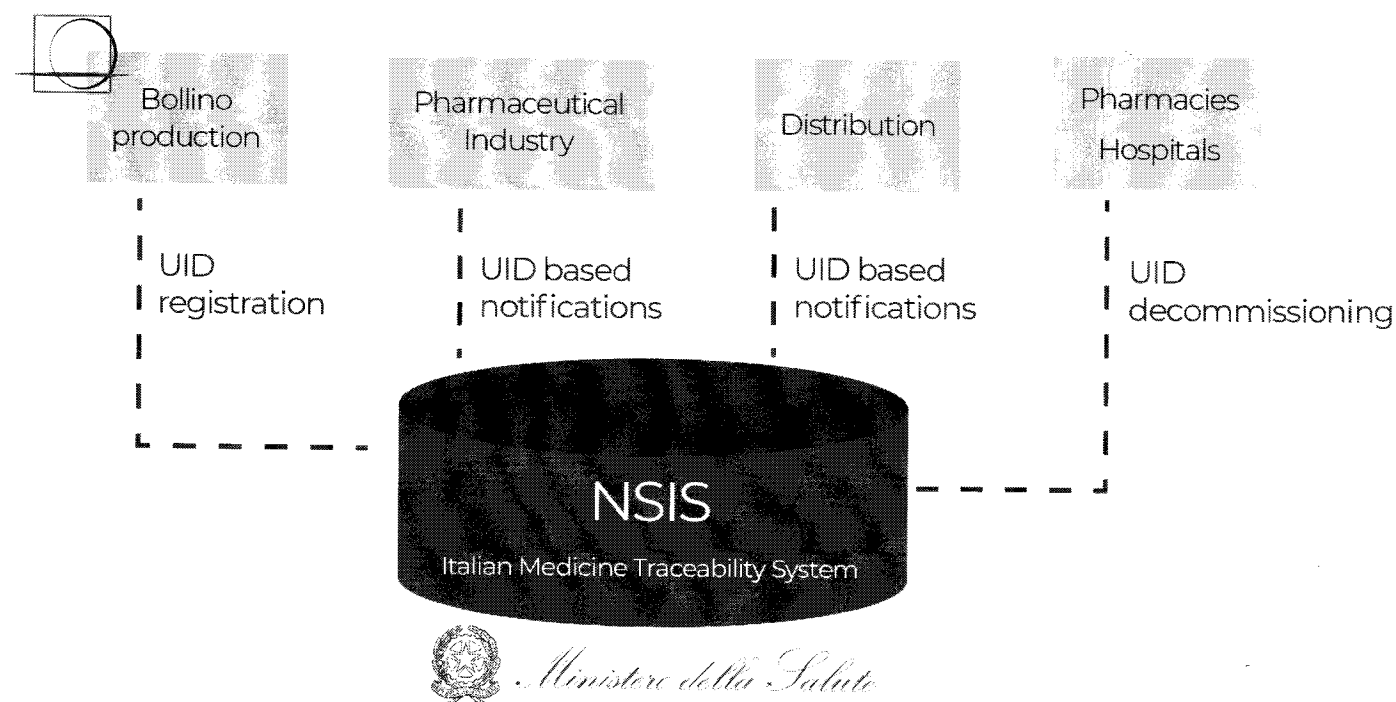
POLIGRAFICO
E ZECCA
DELLO STATO
ITALIANO

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

- o 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;
- o The upper layer shows the following information:
 - o The AIC code in both clear and code 39 barcode form;
 - o The company that holds the AIC in the Italian regulation system;
 - o The name of the medicine with pharmaceutical form, dosage indication and number of dose units;
 - o The unique serial number (UID) in both clear and barcode form.



AIC	●	Medicine marketing authorization code issued by A.I.F.A. (Agenzia Italiana del Farmaco) the Italian National Authority responsible for human drugs regulation.
UID	●	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.
NSIS	●	National Traceability System owned and managed by the Ministry of Health.



Security printing technical features

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.



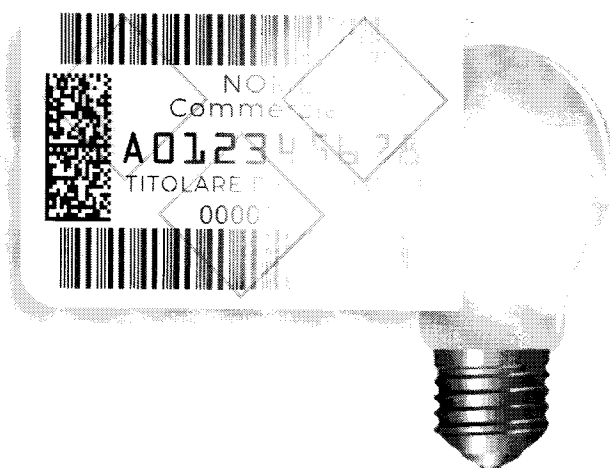
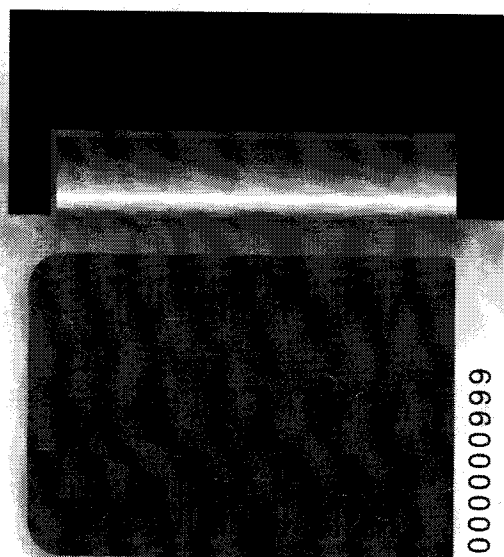
Lower layer:

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



Security checks

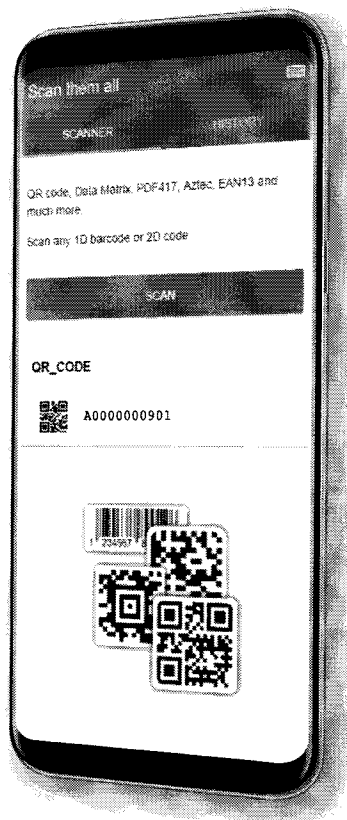
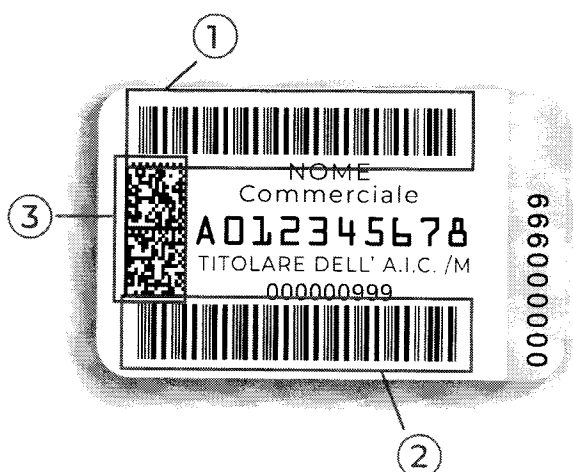
1. UV lamp exposal:
 - a. Security fibers reaction to UV light;
 - b. Paper surface reaction to UV light (UV Dull security element);
2. Watermark shapes visible when the upper layer is held against the light.



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



Poligrafico provides Bollino on behalf of the Italian Authorities, 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