

Pharmico Medical Kft.Date: 30 September 2026

Urgent Field Safety Notice

EVERY UNIT OF THE "ialuril® Prefill" REPACKED KIT LOT E08150 (EXPIRY: 28/08/2028)
AND ANY KIT OR PACK CONFIGURATION CONTAINING AN "IALUADAPTER® / UroDapter®"
DEVICE OF LOT 2300070/20230929

AND

ANY "ialuril® Prefill" REPACKED KIT INCLUDING "IALUADAPTER® / UroDapter®" – LOT:

2100155/20211220
2200068/20220722
2200108/20221222
2300023/20230228
2300070/20230929
2400068/20240430
2400133/20241031
2500119/20251231
2500134/20260130
2600044/20260430

AND ANY (ABOVE WRITTEN LOT) "IALUADAPTER® / UroDapter®" UNIT INCLUDED /
INCORPORATED INTO ANY "ialuril® Prefill" REPACKED KIT

For Attention of*:all distributors, healthcare institutions and professional users in the country concerned to which the affected IALUADAPTER® / UroDapter® devices, or the "ialuril® Prefill" kits containing them, have been supplied – including pharmaceutical wholesalers, pharmacies and online pharmacies, since the kit is also on the market through retail channels. Manufacturer: Pharmico Medical Kft., H-4032 Debrecen, Füredi út 98., Hungary. Direct contractual distributor: UROSYSTEM Zrt., H-1137 Budapest, Szent István park 26. fszt. 2., Hungary.

Contact details of local representative (name, e-mail, telephone, address etc.)*

FSCA/FSN contact: Antal Nagy – Person Responsible for Regulatory Compliance (PRRC), Pharmico Medical Kft., H-4032 Debrecen, Füredi út 98., Hungary. E-mail: prrc@pharmicomedical.hu; copy: info@pharmicomedical.hu · Telephone: +36 30 749 7624
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Physical return of devices takes place only upon the manufacturer's separate written instruction. When so instructed, returns are to be addressed to: Pharmico Medical Kft. – FSCA-PHARMICO-2026/0001, for the attention of the PRRC. Please mark the FSCA number on the package and enclose the completed Acknowledgement of Receipt and Return Form (Annex 1).
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Risk addressed by FSN: unverified manufacturing origin, conformity and full-traceability uncertainty; non-validated downstream co-packing, re-packing and onward packing of the sterile-barrier system, including the opening, prior to end use, of the dual-function collective inner carton (providing mechanical and mild microbiological protection, gamma-disinfected together with the devices, not constituting a sterile barrier system) and the resulting electrostatic contamination-attraction risk.

Action: immediate cessation of the use and further distribution, and quarantine, of the affected devices and of the "ialuril® Prefill" unit packs containing them; the full market withdrawal extends to all pack configurations; physical return upon the manufacturer's separate written instruction. In an "ialuril® Prefill" kit purchased from an online pharmacy and opened before a notary on 17 September 2026 (kit LOT E08150), the manufacturer identified a device of LOT 2300070; the withdrawal covers every unit of kit LOT E08150 – irrespective of the lot number of the device incorporated – and any kit or pack configuration containing a device of LOT 2300070; the scope relating to the ten lots listed is unchanged.

1. Information on Affected Devices*	
1	1. Device Type(s)*
.	Sterile, single-use, non-active urological syringe adapter.
1	2. Commercial name(s)
.	IALUADAPTER® / UroDapter®
1	3. Unique Device Identifier(s) (UDI-DI)
.	0599661700050
1	4. Primary clinical purpose of device(s)*
.	The IALUADAPTER® / UroDapter® is a sterile, single-use adapter intended for the intravesical administration – via the urethra, without the use of a catheter – of a medicinal solution intended for intravesical use or of a bladder irrigation solution from a compatible Luer-connection syringe. The adapter itself contains no medicinal product or irrigation solution. It may be used only in accordance with the approved labelling / instructions for use of the preparation or solution administered and with the local clinical procedure.
1	5. Device Model/Catalogue/part number(s)*
.	IALUADAPTER REF 17001
1	6. Software version
.	Not applicable – the device has no software component.
1	7. Affected serial or lot number range
.	Lots identified with certainty on the basis of Pharmico Medical Kft.'s own manufacturing, release and sales records: LOT 2100155 – manufactured: 20/12/2021; expiry: 21/12/2026; quantity: 175,000 units

	LOT 2200068 – manufactured: 22/07/2022; expiry: 21/07/2027; quantity: 200,000 units LOT 2200108 – manufactured: 22/12/2022; expiry: 21/12/2027; quantity: 325,000 units LOT 2300023 – manufactured: 28/02/2023; expiry: 27/02/2028; quantity: 26,400 units LOT 2300070 – manufactured: 29/09/2023; expiry: 28/09/2028; quantity: 250,000 units LOT 2400068 – manufactured: 30/04/2024; expiry: 29/04/2029; quantity: 76,500 units LOT 2400133 – manufactured: 31/10/2024; expiry: 30/10/2029; quantity: 50,000 units LOT 2500119 – manufactured: 31/12/2025; expiry: 30/12/2030; quantity: 53,120 units LOT 2500134 – manufactured: 30/01/2026; expiry: 29/01/2031; quantity: 25,000 units LOT 2600044 – manufactured: 30/04/2026; expiry: 29/04/2031; quantity: 170,000 units — the withdrawal also extends to any (above written lot) "IALUADAPTER® / UroDapter®" unit included/incorporated into any repacked "ialuril® Prefill" kit Lots 2100155, 2200068 and 2200108 were manufactured and sold under the supervision of the former PRRC (Judit Bodnárné Tóth); verification of their documentation is in progress. Extended scope: Owing to incomplete downstream traceability, the FSCA also extends to any IALUADAPTER® / UroDapter® unit obtained through UROSYSTEM Zrt. or through any other distribution channel that is not fully verified, and whose lot number, original packaging or Pharmico origin cannot be evidenced. Such a unit must be quarantined even if its lot number does not appear in the list above, and the manufacturer must be contacted without delay. Kit lot identified before a notary: "ialuril® Prefill" LOT E08150 (expiry: 28/08/2028; stated on the product box of the kit and on the prefilled syringe; the product box names IBSA Farmaceutici Italia S.r.l. as manufacturer). The kit ordered by the manufacturer from an online pharmacy on 2 September 2026 and opened before a deputy notary on 17 September 2026 contained an IALUADAPTER® / UroDapter® device of LOT 2300070 (manufactured: 29/09/2023; expiry: 28/09/2028) (notarial certificate of facts, case no. 32012/K/722/2026/2.). The product box of the kit bears neither the lot number and expiry date of the device nor a UDI carrier; the lot of the incorporated device therefore cannot be established without opening the kit. The withdrawal therefore covers every unit of kit LOT E08150 – irrespective of the lot number of the device incorporated – and, in addition, any kit or pack configuration containing a device of LOT 2300070, irrespective of the kit's own lot number. The scope relating to the ten lots listed and to any "ialuril® Prefill" kit containing the device remains unchanged.
1	8. Associated devices The adapter itself contains no medicinal product. Syringes, medicinal solutions or irrigation solutions used with it are not covered by this FSCA unless they were placed on the market in a combined pack with the affected adapter – in particular the unit pack marketed as "ialuril® Prefill", into which the device has been incorporated without the manufacturer's knowledge; according to the information available, the preparation placed in the pack is a hyaluronic-acid-based bladder irrigation solution marketed as a medical device. Such unit packs fall within the scope of the full market withdrawal: the entire pack must be quarantined and the manufacturer's written instruction must be requested before any separation. In addition to the device, the E08150 kit opened before the notary contained one "ialuril® Prefill 50 ml" prefilled syringe with plunger rod (manufacturer: IBSA Farmaceutici Italia S.r.l.; LOT E08150) and one Luer-Lock adapter (manufacturer: Primed Halberstadt Medizintechnik GmbH; REF 24041; LOT 02.10.2024). These components are not manufactured by Pharmico Medical Kft. and are not, as such, covered by this FSCA; the kit must nevertheless be quarantined as a whole, without separation of the components.

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem* The deviation was identified by Pharmico Medical Kft. during the documentation review carried out ahead of the notified body's surveillance audit. Four versions of the customer (IBSA) audit documentation dated 9 June 2026, transmitted in partly redacted form via the distributor, contained the wording "for both production sites". Pharmico Medical Kft. manufactures exclusively at its certified manufacturing site at Debrecen, Füredi út 98. The notified body NEOEMKI (NB 1011) confirmed in writing on 28 May 2026 that only devices produced at the certified, audited manufacturing site may lawfully be placed on the market. This contradiction, together with the impossibility of verifying the provenance and version history of the documents,

triggered a non-conformity investigation, a risk assessment and this FSCA. In the course of the discussions initiated to clarify this question it further emerged – first disclosed to the manufacturer on 1 July 2026 – that the device has been incorporated, without the manufacturer's knowledge, consent or advice, into unit packs marketed as "ialuril® Prefill"; the manufacturer holds no technical documentation concerning this assembly operation.

Rev. 6 supplement: The letter of 8 August 2026 from the legal representative of the assembling side confirmed in writing that the co-packing/re-packing activity is ongoing and is intended to be maintained, while at the same time refusing to hand over the validation documentation, the lot-level data and a sample unit. The manufacturer records the applicable requirements: the sterile-barrier system (a foil-paper combination with a semi-permeable paper side, designed and validated for gas [EtO], gamma and steam sterilisation processes) guarantees sterility only within the original factory presentation and the mechanical protection provided therein; the original product is sterilised in its final, closed packaging configuration by gamma irradiation at a validated dose. The performance of the sterile-barrier system must be demonstrated in relation to the complete packaging system and the actual handling and distribution environment (EN ISO 11607-1; MDR Annex I, point 11.4); the assembler must ensure the maintenance of sterility by validated methods (Article 22(3) MDR); an after-the-fact declaration does not substitute for process validation. The outer surface of the prefilled syringe placed in the unit pack in direct proximity to the device is not sterile; its surface microbial load (bioburden) directly determines the microbiological load on the sterile barrier, which is unknown in the absence of testing. Should the individual sterile protective packaging be opened during assembly, the device is not sterile at the moment of use; in that case the factual basis of its classification as a sterile (Is) device ceases to exist, the original certification no longer covers the units so handled, and there is no lawful basis for affixing the CE 1011 marking in relation to such units. For devices placed on the market in a sterile condition, the second sentence of Article 16(2)(b) MDR applies: "Where devices are placed on the market in a sterile condition, it shall be presumed that the original condition of the device is adversely affected if the packaging which is necessary for maintaining the sterile condition is opened, damaged or otherwise negatively affected by the repackaging." Had the manufacturer been informed in due time, it could – as a non-significant change not affecting the legacy status under the decision trees of MDCG 2020-3 (rev.1) – have reinforced the packaging (thicker packaging material or an additional sterile protective packaging), and above all would have participated in the process as a qualified critical supplier, with protocol development and validation; the window for subsequent cooperation was closed by the assembling side's refusal. Under the configuration scheme applied uniformly throughout the documentation: K0 – original configuration (individually packaged device in a sterile barrier system, exclusively together with identical devices, in a collective inner carton sterilised together with the devices and providing mechanical protection – while not constituting a sterile barrier system; the only designed, manufactured and validated state); K1 – opened-collective state (opening of the collective inner carton prior to the place of end use, in an industrial environment, without the manufacturer's prior official information; a non-validated state – the persistence of sterile-barrier integrity can neither be confirmed nor excluded); K2 – kit configuration ("ialuril® Prefill"; not covered by the certification; the resulting sterile-barrier risk can neither be quantified nor excluded).

Physical evidence of the kit configuration: As the assembling side refused to hand over a sample unit, the manufacturer ordered, on 2 September 2026, one "ialuril® Prefill" kit from a public online pharmacy (patika24.hu; operator: Pozsonyi Patika Kft., Budapest), collected it from a parcel locker on 8 September 2026 and opened it on 17 September 2026 in the presence of a deputy notary, under uninterrupted video recording (Notarial Office of Dr. Gábor Hodosi, Debrecen; case no. 32012/K/722/2026/2.). Facts certified by the deputy notary: (i) the transport parcel and the product box of the kit were intact and unopened before opening; (ii) the product box bore the name "ialuril® Prefill", IBSA Farmaceutici Italia S.r.l. as manufacturer, LOT E08150 and the expiry date 28/08/2028; (iii) the product box contained one prefilled syringe (LOT E08150) with plunger rod, one IALUADAPTER® / UroDapter® device in its individual sterile protective packaging, one Luer-Lock adapter in individual packaging and one two-sided instructions-for-use leaflet in Hungarian; (iv) the individual protective packaging of the device lay directly in a compartment of the product box, without the manufacturer's original collective packaging, in the same space as the unpackaged syringe and plunger rod; neither the manufacturer's original collective packaging nor the manufacturer's instructions for use were present in the product box; (v) the individual protective packaging of the device bore the manufacturer's UDI carrier (QR code), LOT 2300070,

	the date of manufacture (29/09/2023) and the expiry date (28/09/2028), whereas the product box bore neither the lot number and expiry date of the device nor any UDI carrier identifying the kit as a whole; (vi) the product box displays, in relation to the device, the manufacturer name "DISPOMEDICOR Kft." and the graphic of the CE 1011 marking – the manufacturer has handed this artwork neither to the distributor nor to the assembler and has not consented to its use; (vii) the components were not fixed inside the product box and moved freely when handled; the transparent top of the individual protective packagings was creased, with no damage visible to the naked eye on the devices inside; (viii) the transport parcel bore no marking indicating a medical device, a sterile product, fragility or temperature conditions, was shipped as an ordinary parcel via a parcel locker, and its contents moved freely inside the parcel; the product box indicates a storage range of 0–25 °C. The deputy notary certified that LOT 2300070 is identical to lot 2300070/20230929 listed in FSN Rev. 7; he did not examine or certify the sterility of the device. This is the first K2 (kit) configuration evidenced by physical proof: the manufacturer's original collective packaging was opened away from the place of end use (K1), and the device in its individual protective packaging was placed, without the manufacturer's original packaging, instructions for use and UDI identification, into a unit pack together with other products (K2). The manufacturer had no knowledge of and gave no consent to this specific repackaging process, and holds no approved protocol or validation for it. A single sample does not prove the composition of the entire LOT E08150; the lot-level mapping data are in the exclusive possession of the assembler.
2	2. Hazard giving rise to the FSCA* For a class I sterile (Is) device the highest-risk – and at the same time gravest – event is the loss of sterility, or even its mere possibility. It is not established at this time whether manufacture at another site or unauthorised repackaging/relabelling has actually taken place. The hazard lies in the fact that the origin, sterility and manufacturing control, biocompatibility, mechanical performance, labelling and conformity coverage of the affected devices cannot be verified with full certainty. A distinct, documented element of the hazard is the opening of the collective inner carton prior to end use: the manufacturer's system is a dual protective system — in addition to the primary sterile barrier, the collective inner carton, closed with self-adhesive tape — itself not constituting a sterile barrier system — provides mechanical protection and a mild but real microbiological protective function; it forms an integral part of the validated protocol; it is not the source of sterility, but it is an unconditional, guaranteed protective element for maintaining the sterile state, and it is itself disinfected by the validated-dose gamma irradiation performed on the final, closed configuration (the bacteria and viruses inside it are destroyed). Opening the inner carton (K1) removes the mechanical protection and at the same time renders the system electrostatically active: the charged polymer packaging surface attracts dust and particulate contamination, which is equivalent to the possibility of carrying bacterial or viral infection; the benefits of assembly in a sterile cleanroom are lost with this opening. This risk can neither be quantified nor excluded; the persistence of sterile-barrier integrity in the opened-collective state (K1) can neither be confirmed nor excluded. Sterility is a property assured by process; retrospective spot-check testing of repurchased stock does not constitute proof of sterility, because the applicable standard is sterility assurance through validated processes. As the device is sterile and applied intravesically, infection, irritation/biocompatibility reaction, injury or inadequate performance cannot be excluded where the origin is unverified. No specific product defect has been identified to date in devices demonstrably manufactured at Pharmico's certified site. If the actions set out in this FSN are implemented, the residual risk is assessed as low. It is further relevant to the assessment of the hazard that the clinical evaluation of the device was prepared for the device as a stand-alone medical device and does not cover the configuration co-packed or re-packed with a syringe or with other products (unit pack). The packaging of the stand-alone device is a single-use sterile-barrier system consisting of foil and filter paper; no validation documentation or test protocol is available as to how this packaging behaves when placed into further packaging together with other products, whether it retains its original properties, or whether the device retains packaging integrity and its sterile state throughout the entire shelf life in the course of the re-packing or co-packing and the subsequent storage and transport. The UroDapter® / laludapter / MID-ii device has been designed, manufactured and validated exclusively for its original configuration (K0: individually packaged device in a sterile barrier system, exclusively together with identical devices, in a collective inner carton sterilised together with the devices and providing mechanical protection); it has been designed and

	validated neither for the opening of the collective inner carton prior to the place of end use, in an industrial environment (K1), nor for presentation in a medical or pharmaceutical unit pack together with products of different geometry and different weight (K2 — kit configuration); the resulting sterile-barrier risk can neither be quantified nor excluded. The E08150 kit opened before the notary evidences, on a marketed unit, the K1→K2 configuration described above: the manufacturer's collective packaging opened, the device in its individual protective packaging without mechanical protection, in the same space as the unpackaged syringe with its non-sterile surface. The presumption under Article 16(2)(b) MDR applies to this configuration; the actual sterility of the device in this presentation cannot be demonstrated. The assessment of the hazard is not mitigated compared with the previous revisions: the condition previously inferred from documents has now been substantiated by the manufacturer with physical evidence.
2	3. Probability of problem arising The probability of an actual non-conformity connected with another manufacturing site or unauthorised repackaging can, owing to incomplete downstream traceability, neither be quantified nor excluded. In view of the lack of information and the potentially serious consequences, a precautionary recall is necessary.
2	4. Predicted risk to patient/users The most serious foreseeable consequences are: urinary tract infection, mucosal irritation or injury, allergic/biocompatibility reaction, inadequate fluid administration or mechanical device failure. The risk can be reduced by ceasing use, quarantine and return. Routine recall of patients already treated is not necessary; in the event of a suspected incident, clinical evaluation and a vigilance report are required.
2	5. Further information to help characterise the problem No quantity estimate can be given: as the IBSA side and the distributor have refused to provide data, the manufacturer cannot establish how many affected devices, or how many "ialuril® Prefill" unit packs, are on the market in the individual countries. The manufacturer has never received official, structured information on the unit-pack operation from any member of the downstream chain: on 1 July 2026 it received catalogue-sheet-type, marketing-oriented materials only, which do not constitute technical documentation. In particular, the following are unknown to the manufacturer: the number of devices incorporated into one "ialuril® Prefill" unit pack; whether the entire delivered volume or only a part of it is incorporated into unit packs; whether the unit packs bear official UDI codes and, if so, what these are (in particular the LOT-level UDI-PI codes); and any correspondence (mapping) between the device UDI-DI/UDI-PI codes and the unit pack's own coding system. Data provision has been refused both by the downstream undertakings concerned and by the distributor — most recently in the letter of 8 August 2026 from the legal representative of the assembling side —; the missing data exist and are in their exclusive possession. Quantities can therefore be established and evidenced at the level of the country concerned only on the basis of the recipients' acknowledgements and of the data provision demanded from the downstream chain. Post-market surveillance (PMS) has, within these constraints, become systemically impossible: the factual precondition of the active and systematic data gathering required by Article 83 MDR is knowledge of the whereabouts of the products, which the manufacturer — owing to the destruction of the UDI carrier in the course of repackaging and to the refusal of data — does not possess. The product box of the kit bears neither the lot number and expiry date of the device nor a UDI carrier; recipients therefore cannot establish the lot of the incorporated device without opening the kit, and identification is based on the name of the kit ("ialuril® Prefill"), the lot number of the kit (E08150) and the presence of the device inside the kit. The quantity, countries of distribution and customers of LOT E08150 are unknown to the manufacturer. The kit could be obtained from a public online pharmacy through a consumer (B2C) channel with parcel-locker delivery; the distribution chain therefore extends, beyond professional users, to pharmaceutical wholesalers, pharmacies and online pharmacies.
2	6. Background on Issue The seven previously identified lots were identified by the manufacturer on the basis of its own release records and its sales records towards UROSYSTEM Zrt.; these are the lots whose onward distribution is documented with certainty. Rev. 6 extended the scope, on the basis of the review of the records of the former PRRC's term of office, by three further within-shelf-life lots (2100155, 2200068, 2200108); verification of the documentation of these lots is in progress. As

	the distributor has not provided complete, verifiable lot-level downstream data and an end-user list, the manufacturer does not assert that the problem is demonstrably confined to these lots. The FSCA therefore extends to any further IALUADAPTER® / UroDapter® device of uncertain origin or with a lot number that cannot be evidenced. Exclusion of a lot — that is, exemption of the given production lot from the scope of the market-withdrawal action (FSCA-PHARMICO-2026/0001) — is possible only upon the documented fulfilment of four conjunctive criteria (expiry of shelf life or absence of shipment; complete LOT/UDI-, customer- and country-level traceability; documented exclusion from the downstream packing chain; approved validation). Upon receipt of any complaint, incident or vigilance signal, exemption of the lot concerned is not permissible — the lot remains within the scope of the withdrawal action — and the signal triggers a mandatory review (Articles 87–89 MDR); the absence of a signal, however, has no probative value in favour of exemption, in view of the documented distortion of the PMS channel. The manufacturer has, by its own means, remedied the assembling side's refusal of data and of a sample through the notarial examination of a market sample. The certified copy of the notarial certificate of facts is sent by the notary to the notified body (NEOEMKI, NB 1011) and to the Hungarian competent authority (NNGYK; case no. NNGYK/49522/2026); a copy is available to the competent authorities of the countries concerned. The four conjunctive lot-exemption criteria are unchanged.
2	7. Other information relevant to FSCA Economic operators concerned and measures: 1. Direct contractual distributor: UROSYSTEM Zrt., H-1137 Budapest, Szent István park 26. fszt. 2., Hungary. 2. Downstream entities of the distribution/assembly chain: not confirmed by the distributor; identified through the manufacturer's own notarial and public-registry research: IBSA Institut Biochimique SA (Switzerland), acting as distributor; IBSA Farmaceutici Italia S.r.l. (Italy), acting as system-pack producer (Italian BD/RDM system-pack registration no. 123042, code S 16691). 3. Manufacturer's measures: suspension of further supply; written demand for complete lot- and customer-level traceability data; stock quarantine and recall; direct customer communication; notification of the notified body (NEOEMKI), the Hungarian competent authority (NNGYK) and the competent authorities of the countries concerned; investigation of the manufacturing origin, repackaging and relabelling; effectiveness checks of the FSCA. 4. Pharmico Medical Kft. is not itself empowered to prohibit the distributor's operation by administrative means; within its own competence it has suspended further product supply and its authorisation of distribution. 5. Competent authority of the direct distributor's country: NNGYK, Hungary. Notification date: 19 June 2026; registration numbers: NNGYK/49522-8/2026; Ref. N.: NNGYK/49522-10/2026. Status of authority measures: in progress. 6. The competent authorities of further countries concerned by the distribution chain are notified as they are identified; in addition, certain further competent authorities have been notified on a precautionary basis (the reference numbers are recorded in the manufacturer's vigilance file). 7. No correspondence (mapping) table compliant with any ISO-certified or standard-based system is available between the UDI-DI/UDI-PI codes issued by the manufacturer and the coding of the unit packs; the existence and values of any official unit-pack UDI codes (including the LOT-level UDI-PI codes) are unknown to the manufacturer. Lot-to-pack traceability therefore cannot be established by the manufacturer from its own records. 8. No information or documented evidence is available to the manufacturer as to whether initial, periodic or shelf-life-related sterility or packaging-integrity tests were performed after the re-packing or co-packing. According to the manufacturer's best professional knowledge, a single sterility test is not in itself sufficient; documented evidence is also required that a validated and controlled packaging, environmental, quality-management, traceability and release system is in operation at the organisation performing the co-packing. No such evidence is available to the manufacturer. 9. (Rev. 6) The letter of 8 August 2026 from the legal representative of the assembling side confirmed in writing that the activity is ongoing and is intended to be maintained, and refused to hand over the validation documentation, the lot-level data and a sample unit. 10. (Rev. 6) The Hungarian competent authority (NNGYK) is conducting a regulatory inspection under no. NNGYK/49522-27/2026 (decision received on 5 August 2026); the manufacturer's data provision and observations are being submitted. 11. (Rev. 6) Regulatory status of the manufacturer: the conformity assessment was obtained in the manufacturer's own right as an initial certification (November 2020); the device is lawfully on the market as a "legacy" device under the transitional provisions of Article 120(3a)–(3c) MDR as amended by Regulation (EU) 2023/607, on the basis of a valid certificate; MDR certification is in progress within the statutory

	deadline of 31 December 2028. 12. Notarial certificate of facts: Notarial Office of Dr. Gábor Hodosi, Debrecen (deputy notary: Dr. Szabolcs Barta); case no. 32012/K/722/2026/2.; dated 17 September 2026; with 40 annexes (photographs, uninterrupted video recording, invoice, order confirmation, approving declaration of the managing director). 13. Further identified actor of the distribution chain of the kit: Pozsonyi Patika Kft. (Budapest; online pharmacy patika24.hu), as retailer. 14. FSN Rev. 7 was dispatched by the manufacturer to the competent authorities of the countries concerned on 2–3 and 10 September 2026; the follow-up FSCA report (Rev. 5) is submitted together with this FSN.
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3. Type of Action to mitigate the risk*		
3.	1. Action To Be Taken by the User* ☒ Identify Device ☒ Quarantine Device ☐ Return Device* ☐ Destroy Device ☐ On-site device modification/inspection ☒ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other ☐ None * Physical return only upon the manufacturer's separate written instruction (see point 6 below). "Other": customer reply and downstream transmission. 1. Immediately stop the use, transfer, sale and distribution of the affected device. 2. Within 24 hours at the latest, identify and quarantine separately the lots listed above, every unit of "ialuril® Prefill" kit LOT E08150 (even without verifying the lot number of the incorporated device), any kit or pack configuration containing a device of LOT 2300070, as well as any unit of uncertain origin or with a lot number that cannot be evidenced. Do not open, repack, relabel or destroy the device. 3. Return the attached Annex 1 within 5 working days, even if you hold no affected device in stock. 4. Forward this FSN within 2 working days to all downstream recipients – in the case of pharmaceutical wholesalers, pharmacies and online pharmacies also to every further reseller – and provide their list and status to the manufacturer. 5. Where the adapter was placed on the market in a combined pack with a syringe, medicinal product or irrigation solution – in particular in the "ialuril® Prefill" unit pack or in any other configuration containing the device in re-packed/onward-packed/co-packed form – quarantine the entire pack and request the manufacturer's written instruction before any separation; such pack configurations, including the "ialuril® Prefill" unit packs, fall within the scope of the full market withdrawal, primarily because the manufacturer holds no certificate for such a unit-pack presentation and the sterile-barrier system is not validated in relation to the receiving pack environment. 6. Physical return: not applicable at this stage. The affected devices must be identified without delay, their use and further distribution suspended, and they must be kept in segregated, secure quarantine. Physical return may take place only upon Pharmico Medical Kft.'s separate written instruction, taking into account the ongoing investigation, the risk assessment and the comments of the competent authority. Should physical return become necessary, the manufacturer will communicate the address, deadline, method, transport conditions and required traceability data in an updated FSN or a separate return instruction.	
3.	2. By when should the action be completed?	Quarantine: immediately, at the latest within 24 hours. Downstream transmission: within 2 working days. Return of the acknowledgement of receipt: within 5 working days. Physical return: not

		applicable at this stage (upon separate written instruction).
3.	3. Particular considerations for: Not applicable Is follow-up of patients or review of patients' previous results recommended? Not routinely If, following the use of the device, a urinary tract infection, pain, bleeding, irritation, an allergic reaction, device breakage or any other suspected incident occurred, clinical evaluation of the patient and immediate reporting of the event are required. Continuity of care and alternative measure: The withdrawal may cause a temporary, local-level supply impact where the adapter is routinely used. The affected device must not be used further. The treating physician should select an authorised alternative on the basis of the approved labelling of the medicinal product or irrigation solution used and the local protocol – for example an appropriate sterile catheter-based intravesical administration procedure or another lawfully marketed device with the same clinical purpose; substitute devices for urethral intravesical administration are widely available, and several preparations of similar purpose containing hyaluronic acid or chondroitin sulphate are available for bladder-instillation therapy (for example Cystistat, Hyacyst, Gepan Instill), with an oral alternative in justified cases. Only the treating physician may decide on postponement of treatment. In the absence of an alternative or in the event of a patient-care risk, immediately notify Pharmico Medical Kft. and the local competent authority.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	YES. The attached Annex 1 must be returned by every recipient within 5 working days, even if no affected device is held in stock. E-mail: prrc@pharmicommedical.hu Subject: FSN-PHARMICO-2026/0001 – acknowledgement of receipt · Telephone: +36 30 749 7624
3.	5. Action Being Taken by the Manufacturer ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None The full, definitive market withdrawal of the affected devices has been in force since 15 July 2026 (entry-into-force protocol PM-DJ-2026/004), as the escalation of the quarantine and suspension of distribution ordered on 16 June 2026. The manufacturer has suspended further supply; ordered the quarantine and recall of the affected devices and of devices of uncertain origin; requested complete lot, stock, end-user and downstream data from the distributor; commenced the investigation of the manufacturing origin, of possible repackaging/relabeling and of the authenticity of the documentation; notified the notified body (NEOEMKI), the NNGYK and the competent authorities of the countries concerned; and monitors receipt of the FSN as well as the quarantined and returned quantities. With Rev. 6 the withdrawal was extended to the three lots of the former PRRC period (2100155, 2200068, 2200108; verification of the documentation in progress), and it has been expressly confirmed that the full market withdrawal extends to the "ialuril® Prefill" unit packs and to every other pack configuration containing the device in re-packed, onward-packed or co-packed form. The withdrawal – while the previous scope is maintained unchanged – expressly extends to	

	every unit of "ialuril® Prefill" kit LOT E08150, irrespective of the lot number of the device incorporated, and to any kit or pack configuration containing a device of LOT 2300070; in the E08150 kit opened before a notary the manufacturer identified a device of that lot. The manufacturer has submitted the notarial certificate of facts to the notified body and to the coordinating competent authority and makes it available to the competent authorities of the countries concerned. In countries where the competent authority's review of the FSN is ongoing, execution is phased: immediate quarantine, with physical return activated by the manufacturer's separate written instruction.	
3	6. By when should the action be completed?	Dispatch to customers in the country concerned: within 1 working day after the comments of the competent authority of the country concerned have been fully incorporated. Follow-up FSCA report (Rev. 5): together with this FSN. Effectiveness checks: event-driven and at each report date. Next follow-up FSCA report – or final report, if the investigation can be closed by then: 15 October 2026. Planned closure of returns: not applicable at this stage.
3.	7. Is the FSN required to be communicated to the patient /lay user?	NO – the device is intended for professional use. The healthcare institution may, however, on the basis of its own clinical judgement, inform the patient concerned where an incident or a patient-specific risk has arisen.
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? Not applicable. The FSN is addressed to professional users; patient-level information is required only in the event of a local clinical decision or a specific incident.	

4. General Information*		
4.	1. FSN Type*	Updated FSN (Rev. 8); in the country concerned – where no earlier dispatch to customers has taken place – it also serves as the first official customer communication.
4.	2. For updated FSN, reference number and date of previous FSN	Previous reference: FSN-PHARMICO-2026/0001, Rev. 7, 27 August 2026. This Rev. 8 incorporates and consolidates the full content of the previous revisions (Rev. 1–7) and, as the consolidated version in force, supersedes and replaces them; all measures ordered under the previous revisions remain in force with unchanged content, and no element of them is adversely affected by this revision. The status of submission to the competent authority and of dispatch to customers varies by country; where the competent authority's review of the FSN is ongoing, dispatch takes place after the authority's comments have been fully incorporated, so that recipients receive clear, uniform and executable instructions.
4.	3. For Updated FSN, key new information as follows:	
	(1) Inclusion in the scope of the withdrawal of every unit of "ialuril® Prefill" kit LOT E08150 – irrespective of the lot number of the device incorporated – and of any kit or pack configuration containing a device of LOT 2300070/20230929; in the E08150 kit opened before a notary the manufacturer identified a device of that lot; the previous scope (ten lots; any "ialuril® Prefill" kit containing the device) is unchanged. (2) Physical evidence of the K1/K2 configuration by notarial certificate of facts (case no. 32012/K/722/2026/2.): the manufacturer's collective packaging and instructions for use are absent, the device lies in the same space as the non-sterile syringe; the product box of the kit bears no UDI carrier and no device lot number/expiry date. (3) Display of the manufacturer name "DISPOMEDICOR Kft." and of the CE 1011 marking graphic on the product box of the kit without the manufacturer's consent. (4) Documentation of the consumer (B2C) availability of the kit through an online pharmacy; express extension of the addressees to pharmaceutical wholesalers, pharmacies and online pharmacies. (5) Factual recording of the further components of the kit (prefilled syringe; Luer-Lock adapter) and their manufacturers, with the statement that these components are not, as such, covered by this FSCA. (6) Update of the competent-authority reference numbers (4.8) and of the reporting dates (3.6; 4.6). Key new information of the previous revisions (Rev. 6–7), unchanged: (1) Notification of three further lots (LOT 2100155, 2200068, 2200108), manufactured and sold under the supervision of the former PRRC (Judit Bodnárné Tóth); verification of the documentation is in progress. (2) Express confirmation that the full market withdrawal extends to the "ialuril® Prefill" unit packs and to every other pack configuration containing the device in re-packed, onward-packed or co-packed form; the primary reason being that the manufacturer holds no certificate for such a unit-pack presentation. (3) Reference to the letter of 8 August 2026 from the legal representative of the assembling side (written confirmation of the activity; refusal to hand over the validation documentation, the lot-level data and a sample unit). (4) Recording of the sterile-barrier requirements on a standards and regulatory basis (EN ISO 11607-1; MDR Annex I, point 11.4; Article 22(3) MDR), documentation of the bioburden load, and the statement that, should the individual sterile protective packaging be opened, the factual basis of the sterile classification ceases to exist, the original certification no longer applies and there is no lawful basis for affixing the CE marking. (5) Recording of the manufacturer's regulatory status (initial certification in its own right: November 2020; "legacy" marketing under Article 120(3a)–(3c) MDR; MDR certification in progress within the deadline of 31 December 2028). (6) Naming of the continuity-of-care alternatives (catheter-based administration; Cystistat, Hyacyst, Gepan Instill; oral alternative). (7)	

	Clarification that, according to the information available, the co-packed preparation is a hyaluronic-acid-based solution marketed as a medical device, for which reason the earlier designation "pharmaceutical unit pack" has been amended to "unit pack". (8) The statement that no quantity estimate can be given owing to the refusal of data by the IBSA side and the distributor; the quantity on the market is not known to the manufacturer. (9) Indication of the regulatory inspection no. NNGYK/49522-27/2026 of the Hungarian competent authority. (10) Inclusion of the dual protective function of the collective inner carton (mechanical and mild microbiological protection; part of the validated protocol; itself gamma-disinfected; closed with adhesive tape) and of the electrostatic contamination-attraction risk arising from its opening. (11) Verbatim citation of the presumption under the second sentence of Article 16(2)(b) MDR. (12) Refinement of the lot-exemption criteria: four objective criteria plus a one-way vigilance gate (excluding any probative value of the absence of signals). (13) Introduction of the K0–K1–K2 configuration scheme (K0 — original configuration; K1 — opened-collective state; K2 — kit configuration) as the uniform conceptual framework of the documentation. (14) (Rev. 7) Addition of the scope-identifier line to the LOT listing: "ANY "Ialuril® Prefill" REPACKED KIT INCLUDING "IALUADAPTER® / UroDapter®" – LOT:" and "AND ANY (ABOVE WRITTEN LOT) "IALUADAPTER® / UroDapter®" UNIT INCLUDED / INCORPORATED INTO ANY "Ialuril® Prefill" REPACKED KIT" — a clarifying amendment without change of substance; the scope itself is unchanged, as the extension to the unit packs is already recorded in fields 2.6 and 3.5.	
4.	4. Further advice or information already expected in follow-up FSN? *	YES
4	5. If follow-up FSN expected, what is the further advice expected to relate to: The follow-up FSN is expected to relate to the outcome of the traceability investigation, the final scope of affected lots and customers, the returned quantities, any incidents, the investigation of the manufacturing origin and of repackaging/relabeling, the outcome of the documentary verification of the extended lot scope, the reconciliation data of kit LOT E08150, the residual risk and the closure of the FSCA.	
4	6. Anticipated timescale for follow-up FSN	Next follow-up communication: at the latest together with the follow-up FSCA report of 15 October 2026, or earlier in the event of material new information. Final closing communication: after all customer acknowledgements, returns and the root-cause investigation have been completed.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Pharmico Medical Kft.
	b. Address	H-4032 Debrecen, Fűredi út 98., Hungary
	c. Website address	pharmicommedical.hu
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * The Hungarian competent authority (NNGYK) has been informed. Notification date and registration: 19 June 2026; registration number: NNGYK/49522/2026. The NNGYK is conducting a regulatory inspection under no. NNGYK/49522-27/2026 (decision received on 5 August 2026); the manufacturer filed its data provision and observations on 15 August and 3 September 2026. Competent authority of the country concerned – reference numbers: Austria (BASG): 9003901572 · Belgium (FAMHP): 45435 · Czech Republic (SÚKL): sukl230564/2026 · Estonia (Ravimiamet): MSO-9/4244 · France (ANSM): R2621519 · Germany (BfArM): 32773/26 · Ireland (HPRA): CRN00HHF2 · Italy (Ministero della Salute): prot. 70166 · Luxembourg (Ministère de la Santé): LU-DM-FSCA-2026-09-10-03 · Malta (Medicines Authority): FSCA084-2026 · Netherlands (IGJ): fame-2608-00091 · Poland (URPL): DNB.444.4565.2026.1.JR · Slovenia (JAZMP): P301-165/2026 · Spain (AEMPS):	

	PS/VCG/LS/8536 · Sweden (Läkemedelsverket): 6.6.2-2026-063078 · Switzerland (Swissmedic): Vk_20260720_024. In addition, further competent authorities (Bulgaria, Croatia, Cyprus, Denmark, Finland, Greece, Latvia, Lithuania, Portugal, Romania, Slovakia) have been notified on a precautionary basis; the reference number assigned by the authority is recorded in the manufacturer's vigilance file as soon as it is available, and is available on request.	
4.	9. List of attachments/appendices:	Acknowledgement of Receipt and Return Form (Annex 1). Copy of the notarial certificate of facts of 17 September 2026 (Annex 2).
4.	10. Name/Signature	Antal Nagy – Person Responsible for Regulatory Compliance (PRRC)
		

Transmission of this Field Safety Notice	
	This notice must be passed on, within 2 working days of receipt, to all those who need to be aware of it within your organisation, and to any organisation – including pharmaceutical wholesalers, pharmacies and online pharmacies – to which the affected devices, devices of uncertain origin or the “ialuril® Prefill” kits containing them (including LOT E08150) have been transferred. Distributors must provide the manufacturer with the complete list and status of downstream recipients, the date of dispatch of the FSN, the acknowledgements of receipt and the return data. Please maintain awareness of this notice and the resulting action for an appropriate period to ensure the effectiveness of the corrective action. The completed acknowledgement form must be returned by every recipient within 5 working days, even if no affected stock is held. Please report all device-related incidents without delay to Pharmico Medical Kft. and, where appropriate, to the national competent authority, as this provides important feedback.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.