Claims:

1. A method of producing a moulded polyurethane hydrogel, the method comprising:

forming a first solution of at least one polyurethane having a molecular weight of between 40000 to 500000 Daltons in a water:organic polar solvent comprising less than 40% (v/v) water;

applying a layer of the first solution to a mould;

drying the layer of the first solution to form a polyurethane film on the mould; and

contacting the polyurethane film with a swelling agent under conditions such that the film forms a polyurethane hydrogel with a swelling agent content of between 1% to 95%,

wherein the polyurethane consists of $–CH_2–(CH_2–O–CH_2)_n–CH_2–[O–OCHN(C_6H_{10})CH_2(C_6H_{10})NHCO–O–(CH_2CH_2–O–CH_2CH_2)–O–OCHN(C_6H_{10})CH_2(C_6H_{10})NHCO–NH–(C_6H_{10})CH_2(C_6H_{10})NHCO–O–CH_2CH_2–O–CH_2CH_2–O–OCHN(C_6H_{10})CH_2(C_6H_{10})NHCO–O]_m–CH_2–(CH_2–O–CH_2)_n–CH_2$ and methyl and/or hydroxyl end groups, and wherein

n is an average independently selected from any number from 1 to 35; and

m is an average independently selected from any number from 15 to 500.

2. The method of claim 1 wherein the molecular weight of the polyurethane is 40000 to 200000 Daltons, 150000 to 350000 Daltons, or 300000 to 500000 Daltons.

3. The method of claim 1 or 2 wherein the polyurethane is derived from polymerisation of 4,4'-dicyclohexylmethane diisocyanate.

4. The method of claim 1 or 2 wherein the polyurethane is a polyether- based polyurethane.

5. The method of claim 4 wherein the polyether-based polyurethane is derived from polymerisation of 4,4'-dicyclohexylmethane diisocyanate and a polyether.

6. The method of claim 5 wherein the polyether comprises one to 35 ethyl ether groups.

7. The method of any one of claims 1 to 6 wherein the organic polar solvent is selected from the group consisting of ethanol, methanol, isopropanol, butanol, tetrahydrofuran, dimethylformamide, dimethylsulfoxide, acetone, acetonitrile and any combination thereof.

8. The method of claim 7 wherein the organic polar solvent is ethanol.

9. The method of any one of claims 1 to 8 wherein the ratio of water:organic polar solvent is selected from 5:95, 10:90, 15:85, 20:80, 25:75, 30:70, 35:65, or 40:60.

10. The method of claim 9 wherein the ratio of water:organic polar solvent is 10:90.

11. The method of any one of claims 1 to 10 wherein a swelling agent is selected from at least one of water, a glycol solution, a hydroxyethylcellulose solution, a paraben-based solution, a glycol-based solution, a glycerine based solution, an oil-based solution, or a silicone-based solution.

12. The method of claim 11 wherein the swelling agent comprises one or more of spermicide, lubricating agent, antiviral, antifungal, antimicrobial, prebiotic, probiotic, microbiome enhancer, flavour compound, aroma compound, sensation enhancing agent, sterilization agent, or disinfecting agent.

13. The method of any one of claims 1 to 12 wherein polyurethane film is contacted with the swelling agent for at least 1 second at ambient temperature.

14. The method of any one of claims 1 to 13 further comprising:

forming a second solution of at least one polyurethane having a molecular weight of between 40000 to 200000 Daltons, 150000 to 350000 Daltons, or 300000 to 500000 Daltons in a water:organic polar solvent comprising less than 40% (v/v) water;

applying a layer of the second solution to the polyurethane film on the mould;

drying the layer of the second solution, wherein the layers form a polyurethane film on the mould; and

contacting the polyurethane film with a swelling agent under conditions such that the film forms a polyurethane hydrogel with a swelling agent content of between 1% to 95%,

wherein the polyurethane comprises $–CH_2–(CH_2–O–CH_2)_n–CH_2–[O–OCHN(C_6H_{10})CH_2(C_6H_{10})NHCO–O–(CH_2CH_2–O–CH_2CH_2)–O–OCHN(C_6H_{10})CH_2(C_6H_{10})NHCO–NH–(C_6H_{10})CH_2(C_6H_{10})NHCO–O–CH_2CH_2–O–CH_2CH_2–O–OCHN(C_6H_{10})CH_2(C_6H_{10})NHCO–O]_m–CH_2–(CH_2–O–CH_2)_n–CH_2$, wherein

n is an average independently selected from any number from 1 to 35; and

m is an average independently selected from any number from 15 to 500.

15. The method of any one of claims 1 to 14 wherein the ratio of n:m is from 1:0.1 to 1:75.

16. The method of 14 or 15, wherein the at least one polyurethane in the second solution is not the same as the at least one polyurethane in the first solution.

17. The method of any one of claims 1 to 16 further comprising applying a subsequent layer of the first or second solution to the polyurethane film on the mould to increase thickness, or to create a specific feature, of the polyurethane film.

18. The method of any one of claims 1 to 17 further comprising applying a subsequent layer of the first or second solution to a portion of the polyurethane film on the mould to increase thickness or to create a specific feature on a portion of the polyurethane film.

19. The method of claim 18, wherein the specific feature formed from the subsequent layer has a different modulus, tensile strength, and/or linear expansion range than the hydrogel formed from the layer to which it is applied.

20. The method of any one of claims 14 to 19 wherein either or both of the molecular weight and n:m ratio, of the at least one polyurethane in the first solution is different to the molecular weight and n:m ratio of the at least one polyurethane in the second solution.

21. The method of any one of claims 14 to 20, wherein additional subsequent layers are applied to increase the thickness to a predetermined value.

22. The method of any one of claims 1 to 21, wherein the moulded polyurethane hydrogel has a linear expansion range of 1% to 100%.

23. The method of any one of claims 1 to 22 wherein the moulded polyurethane hydrogel has a tensile strength of 1 MPa to 100 MPa; 1 MPa to 20 MPa, 20 MPa to 60 MPa, 60 MPa to 80 MPa.

24. The method of any one of claims 1 to 23 wherein the moulded polyurethane hydrogel has an elongation at break range of 200% to 2000%.

25. The method of any one of claims 1 to 24 wherein the moulded polyurethane hydrogel has at least one of a 50% modulus of 80 kPa to 15 MPa, a 100% modulus of 200 kPa to 15 MPa, and a 300% modulus of 700 kPa to 15 MPa.

26. A moulded polyurethane hydrogel condom produced by the method of any one of claims 1 to 25.

27. A moulded polyurethane hydrogel condom, wherein the polyurethane hydrogel comprises a polyurethane having a molecular weight of between 40000 to 500000 Daltons and a swelling agent content of between 40% to 70%.

28. The moulded polyurethane hydrogel condom of claim 27, having one or more of linear expansion range of 1% to 100%, tensile strength of 1 MPa to 40 MPa, elongation at break range of 200% to 750%, and at least one of a 50% modulus of 80 kPa to 15 MPa, a 100% modulus of 200 kPa to 15 MPa, and a 300% modulus of 700 kPa to 15 MPa.

29. The moulded polyurethane hydrogel condom of any one of claims 27 to 28, wherein the condom is substantially impervious to biological agents having an average diameter of 30 nm or greater.

30. The moulded polyurethane hydrogel condom of any one of claims 27 to 29, wherein the condom is substantially impervious to biological agents having an average diameter of 30 nm or greater under simulated usage pressures from atmospheric pressure to 5 kilopascals.

31. The moulded polyurethane hydrogel condom of any one of claims 27 to 30 having an airburst volume of 5L to 50L.

32. The moulded polyurethane hydrogel condom of claim 31 wherein the airburst volume is 5L to 40L.

33. The moulded polyurethane hydrogel condom of any one of claims 27 to 32 having an airburst pressure of 0.75 kPa to 5 kPa.

34. The moulded polyurethane hydrogel condom of claim 33 wherein the airburst pressure is 1.6 kPa to 3.6 kPa.